MEETING

STATE OF CALIFORNIA

HEALTH AND HUMAN SERVICES AGENCY

CENTER FOR DATA INSIGHTS AND INNOVATION

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

FULL COMMITTEE MEETING

FRIDAY, NOVEMBER 1, 2024

8:33 A.M.

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MEETING ROOM 1181

SACRAMENTO, CALIFORNIA 95814

AND

ZOOM ONLINE MEETING PLATFORM

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APPEARANCES

Darcy Delgado, PsyD, Interim chair

Larry Dickey, MD, MPH, Vice-Chair

Allen Azizian, PhD (Present via Zoom)

Alicia Bazzano, MD, PhD (Present via Zoom)

Maria Dinis, PhD, MSW (Present via Zoom)

Catherine Hess, PhD

Jonni Johnson, PhD

Laura Lund, MA

Juan Ruiz, MD, Dr.PH, MPH

John Schaeuble, PhD, MS

Maria I. Ventura, PhD

CPHS STAFF PRESENT

Agnieszka Rykaczewska, PhD, Administrator

Sussan Atifeh, Staff Services Analyst

Sheryl McCarthy

Karima Muhammad

Nicholas Zadrozna (Present via Zoom)

ALSO PRESENT

CalHHS

Agnieszka Rykaczewska, PhD, CDII Deputy Director

Jared Goldman, General Counsel

Maggie Schuster, Attorney

Francis Brown

CDII

Agnieszka Rykaczewska, PhD, CDII Deputy Director

Nick Picinich, Deputy Director

Jennifer Schwartz, Chief Counsel

Olivia Tucker, Legal

Ruben Mejia

CDPH

Michelle Miles, Vital Statistics Branch (Present via Zoom)

Dr. Joshua Endow-Monteiro, Science Advisor (Present via Zoom)

PUBLIC

Evan White, JD/MPP, California Policy Lab (Present via Zoom)

I n d e x

P R O C E E D I N G S

INTERIM CHAIR DELGADO: Good morning, everyone. Happy Friday. Happy one day post Halloween.

MS. ATIFEH: Happy Dio de Los Muertos.

INTERIM CHAIR DELGADO: Good to see everyone. I'm going to go ahead and call the meeting to order. Could those who are remotely participating, members of CPHS, please turn on your camera? That would be awesome. Thank you.

Sussan, could we please do a roll call?

MS. ATIFEH: Sure. Okay, Dr. Dickey?

VICE CHAIR DICKEY: Present.

MS. ATIFEH: Dr. Azizian?

COMMITTEE MEMBER AZIZIAN: Present. Good morning.

MS. ATIFEH: Dr. Bazzano?

COMMITTEE MEMBER BAZZANO: Hi, present. I'm here.

MS. ATIFEH: Good.

COMMITTEE MEMBER BAZZANO: On the phone.

MS. ATIFEH: Dr. Dinis?

COMMITTEE MEMBER DINIS: Present.

MS. ATIFEH: Dr. Hess?

COMMITTEE MEMBER HESS: Present.

MS. ATIFEH: Dr. Johnson?

COMMITTEE MEMBER JOHNSON: Here.

MS. ATIFEH: Ms. Lund?

COMMITTEE MEMBER LUND: Present.

MS. ATIFEH: Dr. Ruiz?

COMMITTEE MEMBER RUIZ: Present.

MS. ATIFEH: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I'm here.

MS. ATIFEH: Dr. Ventura?

COMMITTEE MEMBER VENTURA: Present.

MS. ATIFEH: Okay, the quorum is established.

INTERIM CHAIR DELGADO: Wonderful. Thank you.

Okay, so would just note we are in the month of November, which means we are not reviewing any projects just working on some administrative items. So, again, thank you all for your willingness and commitment to come in an off month to help us get through these administrative items.

I don't really have any Chair updates to discuss, other than what's already on the agenda for Section B. So, I'll just jump into that.

And so, we're on the agenda under Agenda Item B, would like to address the -- or just remind folks that I, from the beginning, have said that I would remain as Chair until the end of this calendar year, which means we need to talk about the next Chair.

So, what you see up on the screen is a -- is part of our policies and procedures that no changes have been made to this section. I'm just putting it up for folks'

awareness that there are criteria for serving as the Chair. The first being that the Chair must be a CalHHS or CalHHS department employee, active employee.

So, the members that are currently fitting that criteria include Dr. Hess, Ms. Kurtural, Dr. Azizian, Dr. Ventura and Dr. Johnson.

In addition, and again if you want to look this is on page 13 of our policies and procedures, the Chair must have been a member of CPHS for at least two years. Which Dr. Johnson comes super close, but not quite hitting that two-year mark, leaving only Dr. Hess and Ms. Kurtural as those members that are both active employees, as well as have been on the board for at least a year.

So, in full disclosure for the -- well, there is a formal process that we'll just overview real quickly, which is that the Chair is nominated by the CDII Director, then voted upon by the Committee. And then that, after that vote the individual's name gets pushed up to the Secretary for approval and appointment.

And so, wanted to -- I've been thinking about this for the last month and have talked to folks. So, wanted to, again in full transparency, knowing that both Dr. Hess and Ms. Kurtural are eligible based on those two criteria.

Carrie's not on the phone, is she?

DR. RYKACZEWSKA: I believe she's absent today.

INTERIM CHAIR DELGADO: Okay. So, I can kind of summarize the discussions I had with both individuals and maybe open the floor for any questions or any other thoughts.

But in talking to Dr. Hess, she had some questions about kind of the time that it would take, the time commitment, but did express an overall willingness. She just gave a thumbs up, for those of you who are on the video screen. An overall willingness and interest in the position.

In talking to Carrie she is, while still fully committed to the Committee is just, in her current position not able to take on more, more roles and responsibilities. And at this time did not express an interest in the position.

Which -- so, just wanted to be fully transparent that those are the conversations that I've had with people.

Dr. Hess, I'll open it up to you, if you want to add anything, or if anyone wants to add anything about potential Chairs.

COMMITTEE MEMBER HESS: I don't have anything to add.

COMMITTEE MEMBER LUND: Are you campaigning? I'm really good with campaigning.

(Laughter)

MR. GOLDMAN: That sounded like the anti-campaigning.

(Laughter)

VICE CHAIR DICKEY: So, just to make sure, you are aware that in terms of protected time they took out -- it used to be you had 20 percent protected time.

COMMITTEE MEMBER HESS: Yeah.

VICE CHAIR DICKEY: That was taken out.

COMMITTEE MEMBER HESS: Yeah, I assume my agency would have to sign off on that, or my department.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER HESS: But, yeah.

INTERIM CHAIR DELGADO: I'd just encourage you, as I did, and as I think most do, before formally acknowledging and accepting to have a conversation with your supervisor about what that might entail. And feel free to ask any questions, or your supervisor can ask questions of us, or of any administrative staff.

COMMITTEE MEMBER HESS: Okay.

INTERIM CHAIR DELGADO: Anybody on the Zoom have questions about this agenda item or anything that we've talked about related to the Chair position?

Seeing none, hearing none, I would also just note that the Vice Chair position does not have the qualifications that are necessary, i.e. the current active

employee or two years.

Instead, we can see up on our policies and procedures screen that the Vice Chair is selected and appointment by the CPHS Chair. So, what we're thinking is that once we nominate a Chair formally, give that Chair time to kind of settle in that they would then select and appoint their Vice Chair.

And the requirement is that the Vice Chair must have been a member for at least one year, and active employment within CalHHS or one of our departments is not a requirement.

So, for those that didn't meet the two-year cut, you meet the one-year cut, so that's exciting. And also, those who are not active employees would also be qualified.

So, we'll just leave that at that for now, but wanted to make sure folks understood that while we will be working with the Director on a nomination for the Chair, this is the process for a Vice Chair to get selected.

Okay, so given that, next steps. So, the next step will be that John Ohanian will present the nomination for the Committee's consideration at the December meeting. The nomination will be Dr. Hess.

And this is not currently a voting item. We will vote on it in December and then seek appointment by the Secretary at the end of the month.

So, any Committee discussion, questions, thoughts on this topic? Okay, no virtual hands.

Oh, do I open it up for public, if we're not voting?

DR. RYKACZEWSKA: Yes, I believe each agenda item.

INTERIM CHAIR DELGADO: Okay. So, let's open it up for the public. Does the public have any questions, or not questions, any comments that they would like to make on this agenda item?

DR. RYKACZEWSKA: Looking for virtual hands and not seeing any.

Nick, do we have any in-person public comment?

MR. ZADROZNA: Not in -- none in person.

DR. RYKACZEWSKA: None in person.

INTERIM CHAIR DELGADO: Okay. Great. So, we will then move on to Agenda Item C. Michelle, I'll hand it over to you.

DR. RYKACZEWSKA: Thank you. So, I want to start off by just acknowledging that I know these are extra meetings that we're having in between our normal bi-monthly events. And it is to address a lot of these administrative items because while myself, my team, others can start drafting items, we do our best thinking, the reality is it really needs your expertise, your experience to really make them be the processes that we're building, and being

address, that we're putting together really strong. So, we do our best thinking, but recognizing that we probably miss think, they're probably not perfect.

And really hoping for many of the items that we have on our agenda today, looking for you to help us to see where things resonate and align, where things maybe don't resonate, or we missed things so that we can really strengthen our administrative processes and approaches.

So, the first of these has to do with we've been working very closely with the California Department of Public Health. So, I actually have a couple of introductions to do.

First is Michelle Miles, who is the Vital Statistics Branch Chief. Michelle, are you on our Zoom? Oh, you might need to say something so it pops you up.

MS. MILES: Yes, hello. Hello, how are you all?

DR. RYKACZEWSKA: Thank you, Michelle.

And then, we also have Joshua Endow-Montero. I hope I said that right, Joshua, I'm sorry. Who is our CDPH Science Advisor. And say hello.

DR. ENDOW-MONTEIRO: Hello, close enough.

DR. RYKACZEWSKA: Okay, sorry.

So, we're here today because our two teams, the CPHS admin team, as well as CDPH's team, have been meeting because so many of our projects are related and involve

CDPH. And in particular, very often Vital Records data.

And we set up recurring meetings because sometimes we realized, oh, some certain projects were getting stuck and we had the opportunity to kind of talking about, wait, we were waiting on your letter of support. But, wait, we were waiting on this. And to work through some of those issues to troubleshoot and to essentially facilitate collaboration among our teams to help move projects.

And so today, based off of a lot of these conversations there are three items we'd like to put forth for the Committee's consideration and feedback.

The first is the proposed workflow between CDPH and CPHS. And again, this is coming from a lot of the conversations where we've been having, trying to get clarity about what comes first, what comes second. How do we work together on these applications.

In addition, CDPH has drafted letters of support and we're looking for your feedback to make sure that there is nothing missing from them or that they resonate.

And then, we were hoping to have a discussion around the Vital Records five-year rule. We've been trying to dig into that a little bit more and to make sure that we're understanding what it is and to talk about how do we then implement, what do we do to make sure that we're following that.

So, there's the three pieces we'll be working through in this conversation.

So, I'm going to start with the work flow. So, this actually started with -- it was the starting point on a lot of conversations when the motions around letters of support came up. And the reason these conversations started was because of CDPH let us know that there are some Vital Statistics -- sorry, I just want to make sure I'm pulling up the right thing.

There are some Vital Statistics statutes that they had raised concerns about when it came to letters of support. So, I am displaying those on the screen now.

Can we minimize the video just for a second, so that we see those on the screen. And they are included in your packets, as well.

So, as I said, one of the things that we were noticing that often led to projects being stuck was a missing letter of support and we got to dig into this.

And so, one of the things that a lot of the Vital Statistics statutes were saying is that -- in particular, you can see it, and highlight this section here in the second one -- that it first be reviewed by the appropriate committee constituted for the protection of human subjects.

And so, there was this question of, from CDPH, how can we give a letter of support when our statute says that

you have to review it first. And there was a sequencing question that started this conversation.

And so, in an attempt to kind of clarify and streamline that review process between our two entities, we drafted a proposed work flow and are hoping to get your reactions to that, thoughts, feedback so that we can revise it further.

COMMITTEE MEMBER LUND: I just -- I can clarify how the current process happened in regard to the second item.

DR. RYKACZEWSKA: Uh-hum.

COMMITTEE MEMBER LUND: So, it used to be, I'm going to go in a galaxy far away, but CPHS did the reviews and then the review process started at CDPH. And what was happening to researchers, because it took so long for our group, and then it took so long for the VSAC, that six months later they finally had two approvals, right.

So, years ago when Jim Greene, Dr. Jim Greene was State Registrar, he and Dr. Ruiz met and agreed on the current process where there could be concurrent reviews, but the CPHS approval should come first before the VSAC approval. And Dr. Greene agreed at the time that that satisfied this requirement that this review was first, but it didn't -- it saved researchers like three or four months in the process.

So, just to let you know that's how that happened.

DR. RYKACZEWSKA: That is very helpful. And I think we're keeping that, the concurrent aspect. And I can actually go ahead and pull it up.

COMMITTEE MEMBER LUND: Yeah, I'm sorry, I didn't mean to jump in. I just --

DR. RYKACZEWSKA: No, this is helpful.

COMMITTEE MEMBER LUND: -- before you moved on, I wanted to make sure people understood how we got where we are.

DR. RYKACZEWSKA: So, let me -- so, I think where we're trying to get to is like one more layer of specificity in terms of what does it mean for concurrent to occur.

And so, again, included in our packets is this work flow that we are proposing, where it still incorporates some of the letters of support, some of the things that we typically see.

But again, this is just our best thinking at the time, but looking for your feedback to see what resonates and what doesn't.

VICE CHAIR DICKEY: Maybe you want to walk through it.

DR. RYKACZEWSKA: Yes, absolutely. So, yes, let me walk through. So, the starting point is here on the left side. And this is where say, okay, researchers would like

to use Vital Records data. That's kind of the starting point, they're recognizing that.

And so, to your point, Ms. Lund, we are looking at them to concurrently start, there on the top, their Vital Statistics application, and on the bottom their CPHS application at the same time.

And we're asking them to attach copies of both to the original applications, so CPHS can see, yup, they've submitted their Vital Stats application, and then Vital Stats can also, CDPH can see updates. They've done their step of submitting the CPHS application.

Then we start the reviews. So, for CDPH, we're saying they're going to complete a preliminary review of the application, primarily for completeness, to make sure that everything that needs to be in there is in there.

At the same time our admin team will complete the pre-screening process, also looking at is it complete.

Based off of if our prescreening at CPHS is successful, if everything that needs to be in there is in there, that would then -- our staff would assign the application to a CPHS reviewer. And, of course, members, Committee members would be looking at that application.

And here's a little bit of a difference in, I think in process, but again really happy to hear your feedback, is oftentimes where we were seeing some of the

delays tend to be we're waiting for a letter of support.

And so, what I would like to recommend is that the CPHS reviewers, so our Committee members, review it potentially without a letter of support attached, and recommend a deferred approval. Meaning we're still pending, recognizing that we're still pending the CDPH letter of support.

And then, once that letter of support does come for new projects, at that point the researchers would attach it and the final like -- and again, so it's like the only thing we're waiting on is the letter of approval, once that letter of approval is attached then, to make things easier the administrator, the CPHS administrator, which in this case is me, would approve that -- send out that final approval letter saying, yes, we've finally received the letter of support, we can move this application forward.

And so, that's slightly different and it's really mostly intended to save you that step of having to constantly check whether that letter of support has been attached. Because I know a lot of the times those applications sit in your dashboards for a while just waiting on that final step. So, it would allow you to clear out your dashboard and --

VICE CHAIR DICKEY: So --

DR. RYKACZEWSKA: Uh-hum.

VICE CHAIR DICKEY: -- is there a way to do that in IRBManager so that it --

DR. RYKACZEWSKA: I believe so. There's a few ways we're exploring. Some more manual than others. So, one kind of potential middle ground would be to say when the reviewers note, they have -- there's that textbox at the end, to note deferred approval pending letter of support. And that would then allow us to reassign it to the administrator to finalize it.

And then, looking at more complicated fixed to IRBManager in the long term, as well.

VICE CHAIR DICKEY: But for us to keep moving we have to do a deferred approved, and then put a note in the file.

DR. RYKACZEWSKA: Yes.

MS. ATIFEH: Agnieszka, actually it doesn't -- it doesn't say in the application to researchers to attach that.

DR. RYKACZEWSKA: So, they would go back to data entry, we'd have to push it back.

MS. ATIFEH: Would the reviewers have to select clarification at this point?

DR. RYKACZEWSKA: Yes.

MS. ATIFEH: Yes.

DR. RYKACZEWSKA: Oh, sorry, yes that's true. So,

within the IRBManager options it would -- the drop down would still be clarifications needed. But then in the textbox to be there, all that's missing is the letter of support.

MS. ATIFEH: Yes, that's right.

DR. RYKACZEWSKA: Then we could reassign it. That's a very good point. Thank you, Sussan.

COMMITTEE MEMBER LUND: So, I think this is a great idea. I am so tired of going back in and having to approve things just like the letter of support, okay. So, I think this is a great idea. It's consistent with what we ask for in a letter of support. We don't need to know whether or not VSAC has approved. What we need to know is whether the agency is going to release the data for the purposes of this research study in compliance with all of the laws.

So, if that's -- if that's what CDPH will be looking in the letter of support, then I think that this works and I think it's streamlined. So, I think it's a great idea.

DR. RYKACZEWSKA: Okay. So, then let me finish, then, our workflow. So, once CPHS releases the CPHS approval letter, that would then get attached into the Vital Statistic application and at that point CDPH would complete their comprehensive review. Which would include review by

the Science Advisor, VSAC if necessary, assuming it's Vital Records data, and the State Registrar. So, that's the point at which CDPH would do that comprehensive large review.

Assuming everything moves beautifully, CDPH would then release the approval letter which would enable them to go to the next step of CDPH extracting and preparing the data as appropriate, and finally releasing that to -- through a secure access to the researchers.

Now, I do want to call out there is -- that's not the end. On an ongoing basis, there is an annual CPHS continuing review that, then once approved, leads then to CDPH so that they see that, yes, CPHS is continuing to approve this project. And so, that would continue.

Now, the final piece that I do want to just call out and then open it up for you, for some more discussion and, of course, for any comments from CDPH, is that when an amendment is submitted it would largely follow the same process where they would have to submit the amendment to us, they would have to submit a continuing application to CDPH.

Except in those cases, we would not receive a new letter of support from CDPH because that is only when we have a new project. So, that piece would be a little bit different where there is, again, concurrent approvals of the amendment happening, but a little bit less back and forth between our two groups.

Michelle, Joshua, did I miss anything from our discussion?

MS. MILES: No, I don't think so. I think that you've covered great. You've pretty much covered what we had discussed.

DR. RYKACZEWSKA: All right.

MS. MILES: But I will defer to Joshua if he thinks that you might have missed some things.

DR. ENDOW-MONTEIRO: I think you covered everything that we've discussed.

DR. RYKACZEWSKA: Perfect. I actually just remembered one more piece, and I remember this when I read the note at the bottom of, if any changes are made during the review process, both applications will need to be updated.

And one of the things that we talked about was when do we compare the two applications together. And we have given access to CDPH staff to our IRBManager, so they can actually go in and see the latest and greatest of our applications within our system. So, that when they see that their approval letter has been released by us they know, okay, now this is the final version that's in IRBManager. And they, as part of their comprehensive review, they do a comparison of the two applications to ensure that they're in alignment.

Okay, I'm seeing Michelle and Joshua nod, good, I'm saying that correctly.

So, yes, so opening up to anything we've missed, anything that resonates or doesn't resonate.

COMMITTEE MEMBER LUND: So, CPHS -- CDPH will do that comprehensive comparison review so that reviewers here don't have to do it? And we can assume that they will let us know if they find any differences we should be aware of?

DR. RYKACZEWSKA: Just checking in with Michelle and Joshua, is that --

MS. MILES: I'm sorry, I couldn't hear that question.

COMMITTEE MEMBER LUND: Hi Michelle. It's Laura.

MS. MILES: Hi Laura.

COMMITTEE MEMBER LUND: Hi. So, I'm -- my question is, so CDPH will do the comprehensive review between what's submitted to VSAC and what's been submitted to CPHS to ensure that those two applications are consistent with each other. So that reviewers, individual reviewers here at CPHS don't need to do that comparison?

DR. RYKACZEWSKA: Just repeating the question, just to make sure we're hearing. I believe, and please correct me, the question is confirming that CDPH is doing the comprehensive comparison between the two applications so that our CPHS reviewers don't have to do that comparison

during their review.

MS. MILES: I think the answer to that is that we do that comprehensive review to ensure that the CPHS or the two applications mirror each other. We will do that once we get the approval from CPHS. So, when you've completed your review, had the researcher make any changes necessary to the application, we can then -- and the researcher then attaches that document to our application, we will make sure that our application matches the CPHS application.

COMMITTEE MEMBER LUND: So then, Michelle, this is Laura again. If there are differences, what do you do?

MS. MILES: Well, hopefully, at that point you've already done your review and had them make any changes you see necessary or the Committee sees necessary. We will make sure that our application mirrors that, so that those applications are the same, they're one in the same.

COMMITTEE MEMBER LUND: Right. So, I guess my question is, because I'm trying to find out on this side, because the reviewers have been here, individually comparing the VSAC application to the CPHS application, and we only need to do so much redundancy.

So if you, at CDPH, are comparing the final approved CPHS version with the version submitted to VSAC, if you find differences do you then ask the researcher to make the VSAC application consistent with what CPHS approved, or

what do you do?

MS. MILES: Yes, that's exactly what I was saying, Laura.

COMMITTEE MEMBER LUND: Okay.

MS. MILES: That's why we are not moving forward. Once we give you a letter, the Committee a letter of support, our review will stop until we've received that approval from the CPHS Committee. At that point you've already gone through, made any changes you see necessary. And then, as we're completing our comprehensive review, we will take your final review, your final application and make sure it matches the VSAC application.

If it does not, we will ask the researcher to change the VSAC application to mirror what the CPHS application looks like.

COMMITTEE MEMBER LUND: Great, that was the information that I was looking for. Thank you. So, it sounds, Agnieszka, like you've had conversations here with the Committee about how deep a dive do individual reviewers need to do in comparing VSAC with CPHS. And it sounds like with the workflow and the new information that reviewers here, part of our process as reviewers, and I'm throwing this out to the Committee for discussion, our process as reviewers is to check to make sure that that VSAC application is attached, but that we don't need to do the

comparison. We can just look at what they're proposing to us, approve or not, or whatever we do with that as reviewers. And then, when it moves to CDPH they'll be responsible for that comparison to make sure that the applications are mirrored. Okay.

VICE CHAIR DICKEY: I just want to --

MS. MILES: That's correct, Laura.

VICE CHAIR DICKEY: It might happen that you discover there's something you want changes and it's unacceptable to VSAC. In which case, I'm assuming you would notify the researcher of what you'd like changed, and they would have to reapply to us to get us to approve that, so that the two are the same?

MS. MILES: Joshua, can I have you step in?

DR. ENDOW-MONTEIRO: I think I can, yeah. So, I think that (indiscernible) -- so one of the reasons for this change and the clarification of the process is that what we were getting is that we were tasked to -- if there was any change made by CPHS, it would have to go through our whole review process again. And since that was happening multiple times where changes were made after we had reviewed everything, so we had to go back, and we had to make sure everything consistent. That's the part of the reason for this clarification because we are reviewing them concurrently, changes were being made by either side, and we

weren't sure where it was on each side.

VICE CHAIR DICKEY: Right.

DR. ENDOW-MONTEIRO: To answer your question, when we review it first I think we have a preliminary screening that's just making sure to make sure the materials are there. Then we have a research review that does go to your CPHS portal, concerns that your application is -- the current version of your application is the same as our application that's in our system, that they provided us.

And then, on the -- sorry. And then -- I mean I'm the Science Advisor. And as Science Advisor I do carefully review that -- those applications are the same. Sometimes that change will be in our system to be consistent with your approval.

But as you've mentioned, sometimes what they've told you is not consistent with they are requesting. And they need to -- in those cases, we require and ask them to update their application to you. They have to go back and make those changes with CPHS. Because, for example, they've told you that they've requested no identifiers, but they're requesting addresses, and names, and other identifiers.

So, we make sure that applications are consistent and absent that material that that information's necessary for their project. We request them to go back to you and they need to get confirmation that you have approved those

changes.

COMMITTEE MEMBER JOHNSON: So, that yellow box would then filter back over to the green one.

DR. RYKACZEWSKA: That's right. So, yes, in case there's audio issues, this yellow box, should there be something where they need to update the CPHS one, they would then submit an amendment and that would go back to this pre-screening. We would screen the amendment and send that through.

COMMITTEE MEMBER LUND: It would help to actually, if we could make that modification to this just so it's institutionalized, and we remember that's what's going to happen.

DR. RYKACZEWSKA: Uh-hum, absolutely.

VICE CHAIR DICKEY: And also, maybe the text at the bottom, maybe specify that in the text.

DR. RYKACZEWSKA: Yeah, down here. Yeah. Okay. Yup.

COMMITTEE MEMBER DINIS: So, I had one question. Is this a situation where both -- is it like a combination of IPA and the IRB? As I understood before on your regulations, on the first page it seemed like there was also mention of regulations from IRB.

COMMITTEE MEMBER LUND: So, I think, Maria, it could be either because it's just a request for Vital

Records data. So, it could be a request that we are reviewing under IPA, or it could be a Common Rule request, depending on who the requestor is.

VICE CHAIR DICKEY: And it's not going to matter to VSAC.

COMMITTEE MEMBER LUND: Right, it won't matter to CDPH.

COMMITTEE MEMBER DINIS: Right, because I just saw that here, so that's why I wondered okay.

DR. RYKACZEWSKA: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: I have two concerns. One is the language concern, and one is substantive. The language concern, which is a small one, the box in the upper left-hand corner, the word "system" seems to me to not belong in that sentence. I would think it should simply say "attach .pdf copy of CPHS application to Vital Statistics application", not with the word "system" there.

DR. RYKACZEWSKA: We can, I think, make that change. I think that makes sense. Because, really, it's part of the application to CDPH and it's the Vital Statistics application. So, I think we can make that change.

COMMITTEE MEMBER SCHAEUBLE: And without the word it would be parallel to the box at the bottom, which has the wording for the application here.

The substantive matter is I am -- I'm troubled by a couple of things in the logic of this process. The second box at the top says, "CDPH is reviewing the application for completeness". And that doesn't provide the information that I think reviewers have really been looking for, which is knowing that from a preliminary reading the agency expects that the data could be released pending the final review process. Limiting it to completeness I think is not -- for me, at least, not what we're really looking at here.

And then, it seems very cumbersome to have this flow chart showing that CPHS will do its review without even receiving a letter from the agency and only afterwards will the letter be attached. So, any indication of where CDPH is in this process is unknown to us at the time that we are expected to do our review.

It adds an extra step in there to do a deferred approval, add a letter later on, and only then allow the process to go back to CDPH.

And I really am wondering why, why we should have to wait that long to get a letter of support from CDPH.

COMMITTEE MEMBER LUND: Could I? So, I know, it's very cumbersome. And it's -- this is a unique situation to Vital Records data. Other state agencies don't have this process because of the requirement in statute about VSAC. VSAC is not part of CDPH. It's not employed by CDPH. It's

an advisory committee that CDPH runs in order to approve the applications.

So, at the time that we're doing the concurrent reviews VSAC hasn't met, yet. And one of the reasons, as I mentioned earlier in the meeting, that we went with this concurrent review is that in the past we did the full review, and then lobbed it over the wall to CDPH, and CDPH and VSAC did their review, and six months later researchers got two approval letters so they could move forward. And this phase, literally three to four months for researchers in getting their Vital Records data.

So, CDPH can't give us the letter of support based on VSAC until VSAC meets. And they meet every other month, the same way that we do.

COMMITTEE MEMBER SCHAEUBLE: But could they not give us a letter saying that pending approval from VSAC, CDPH anticipates it would be willing to release the data?

COMMITTEE MEMBER LUND: I think that that is the intention.

VICE CHAIR DICKEY: That's it right there.

COMMITTEE MEMBER LUND: Yeah, I think that's the intention.

COMMITTEE MEMBER SCHAEUBLE: But the flow chart simply says they're checking for a completeness of the application, nothing else.

VICE CHAIR DICKEY: Can I suggest something? I think there's a missing box there. Maybe that would help you.

COMMITTEE MEMBER SCHAEUBLE: Okay.

VICE CHAIR DICKEY: Of what their process is before they issue the preliminary letter of support. Just like we have a box that says "CPHS Reviewer completes", there's somebody that's in that space right there for CDPH deciding that they can issue a preliminary letter.

And who would that be, and could we put that box in?

COMMITTEE MEMBER LUND: Joshua, can I ask -- this is Laura, can I ask you a question? This box, where it says "completeness", it might help if you could explain what completeness includes. Does that include not only paperwork completeness, but also that you have reviewed for statutory compliance so that you would be able to provide a letter of support that says the things that we would want to hear as a Committee?

DR. ENDOW-MONTEIRO: I do think there is a missing box here. There is a manager review --

COMMITTEE MEMBER LUND: Okay.

DR. ENDOW-MONTEIRO: Sorry, let me --

MS. MILES: Yes, there is a manager review that happens before that letter of support goes through. So, I

guess we could include another box there that indicates that, you know, that letter of -- or, we could put it in that same box. That the letter of support, not that one, but the one about providing the letter of support that, you know, CDPH has reviewed for statutory alignment or something to that effect.

Would that help the Committee?

COMMITTEE MEMBER LUND: Does that address your concerns, Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: It would certainly help as far as knowing that CDPH has looked at more than simply the completeness of the application.

I'm still wondering why we have to wait on receiving that letter until after we have completed our review. Why does that have to come after we're done?

I mean, VSAC is going to do its review later on anyway, so that's not at issue here.

VICE CHAIR DICKEY: I think it's the issue the statute says CPHS will review this first. And so, they need some action from us before they can do anything.

DR. RYKACZEWSKA: And that, I think, was the crux of our conversation was the space around trying to --

COMMITTEE MEMBER SCHAEUBLE: So, you're interpreting that as even a preliminary letter --

DR. RYKACZEWSKA: Yes.

COMMITTEE MEMBER SCHAEUBLE: Would be too soon if it came before CPHS review?

DR. RYKACZEWSKA: I think that was the concern being raised by CDPH that because this very explicitly says first be reviewed by CPHS, that that was why we were wanting to have this be complete.

And I don't want to -- Michelle, Joshua, I don't want to speak for you, so if it's different, please correct me.

COMMITTEE MEMBER SCHAEUBLE: So, in effect, then, we as reviewers are going to have to assume that CDPH will be approving and if that's not true, we'll find out later on is basically what it amounts to.

VICE CHAIR DICKEY: They'll notify the researcher and they'll have to come back to us.

DR. RYKACZEWSKA: They would notify the researcher. And I think partially because, and again just pointing out that part of what they're supposed to be doing is comparing our findings, which is part of why they're comparing the two applications.

And so, they're looking for us to provide some information that we support it, so that they can review that, make sure that all of the changes have been made, and then based off of that, taking that into account, have that inform their decision making, as well.

Oh, and I see, Joshua, you've got a hand.

DR. ENDOW-MONTEIRO: Yes. And just to clarify, VSAC in general will only be reviewing the requests for birth and fetal death data. For death data, you are still so -- (indiscernible) -- so, in the past you can see that CPHS' role in death data is determining whether this individual, or this researcher is able to receive the data, and there are persons expressing a solid scientific interest.

So, to meet this, we need you to say that they have a valid scientific interest before we can say we can release the data. So, I think that's one of this, one of the reasons. So, for death data we need CPHS to say that this -- these individuals have a valid scientific interest.

For birth and still death data we, as mentioned in I think it's the second box, the second item there, that states that for birth and fetal death data the VSAC needs to review that first. Those findings then need to be reviewed by VSAC. And then, VSAC needs to the State Registrar that the information shall be released.

VICE CHAIR DICKEY: So, the death data never goes to VSAC? Does --

DR. ENDOW-MONTEIRO: So, in general the death does not go to VSAC. The conditions are, because VSAC is actually a committee. There is a Vital Statistics Advisory

Committee which is mostly involved with birth and fetal death data. And there is a Vital Records Protection Advisory Committee that does birth or (indiscernible) -- I don't know how we say it, we just call them VSAC Joint Committee.

And in that role they have recommended that most datasets, such as the CCR-linked, because the California Cancer Registry linked that data, and the HCAI-linked death and the HCAI-linked -- well, based on the cohort is going to come through anyway, the birth data. But the HCAI-linked death data, they go through them, and they have the opportunity to review them.

VICE CHAIR DICKEY: But that's not VSAC -- I mean it's they're using -- they're just looking at do we say it's a valid scientific interest, right?

DR. ENDOW-MONTEIRO: Yes.

VICE CHAIR DICKEY: Yeah. We had one of these, and I can only remember one that we turned down, it was somebody selling tombstones.

(Laughter).

VICE CHAIR DICKEY: And marketing, and we turned that one down because it wasn't valid scientific.

MS. ATIFEH: Following up on one earlier comment from Laura, in the past there have been occasions where in looking at the application to us and the application to

VSAC, I and other reviewers have seen differences in, for example, what years of data were being requested or what variables were being requested. And the discussion earlier was saying that those discrepancies would be sorted out later on in the process here.

But I'm also thinking that we may need to, nevertheless, look at least somewhat into the VSAC application because we may want to be requesting something different in the CPHS application if we really see discrepancies of that sort.

Would you agree with that, Laura?

(Whereupon, the recording audio goes out for several seconds.)

COMMITTEE MEMBER LUND: Okay, it sounds to me, with the proposed workflow and with Joshua's description of their process after they get CPHS approval, that we don't need to do that. Because they will not release data if we haven't approved what's been described.

So, if VSAC, the application in the VSAC, if the VSAC application looks different than what we approved, they will take the responsibility for working with the researcher to make the changes to the VSAC application to mirror the CPHS application, or they will request that the researcher submit an amendment to make changes to the CPHS application.

So, based on my understanding of what I'm hearing

here, it would be okay, and this is me who looks at everything twice, it would be okay for us to just review, to ensure that the VSAC is attached, but to just review the CPHS protocol as submitted, and then provide it to CDPH for them to do the comparison.

DR. RYKACZEWSKA: And I just --

COMMITTEE MEMBER SCHAEUBLE: Would it be wrong to look at the VSAC application?

COMMITTEE MEMBER LUND: Oh, I don't think it would be wrong, no. I just don't think that we need to take on the responsibility of doing that. But I think reviewers should do that, if they feel they need to as part of the review.

VICE CHAIR DICKEY: And they're attaching it to it right?

DR. RYKACZEWSKA: And I see a hand from Joshua.

DR. ENDOW-MONTEIRO: Just one comment is I would expect, based on because we're working on a concurrent review, and we were tasking different things, that I would expect if CPHS did not look at our application there are likely items that will be missed in that initial review, and there will be more back and forth. Because we won't be able to catch items that are pretty obvious in their application. And then, they won't be able to flush those until we point them out and, likely, they'll need to revise what they told

you because is not consistent.

COMMITTEE MEMBER SCHAEUBLE: I think I was raising the question because very often there have been inconsistencies in different places within the CPHS application. And I've gone to the VSAC application to see what was said there to try to sort out why there were inconsistencies in the CPHS application.

DR. RYKACZEWSKA: So, it's almost like the attached VSA -- I don't know how to say it -- VSA application, the VSAC application is almost like an additional source of information to help clarify some of the responses that the researchers are providing.

COMMITTEE MEMBER SCHAEUBLE: Yes.

DR. RYKACZEWSKA: I mean in my perspective it makes -- I don't think there's any issue in looking into the application for more information to try to help clarify what it is that the researchers are proposing.

I think what we're saying is it's not the -- it is an option, but not the responsibility of the CPHS reviewer to do that comparison.

COMMITTEE MEMBER SCHAEUBLE: Okay.

DR. RYKACZEWSKA: So, I think always using all of the information that is at our hands to help inform our discussions with the researchers, absolutely we should, anything we have access to is there for our information.

And so I think -- don't think there's anything that precludes reviewers from taking a look at it to see if they can get more sense of what's in there.

I think it's more of that -- clarifying that the responsibility of making sure that both align is on the side of CDPH.

COMMITTEE MEMBER SCHAEUBLE: Understood.

COMMITTEE MEMBER LUND: Do we need to provide perhaps a little more information for researchers so that they know that the application -- I know we have something in there that tells them that they should be the same, but that really clearly states, you know, if you go to CDPH with your request and it's different than what we've approved you will have to submit an amendment. You know, it's going to take your time to do it.

VICE CHAIR DICKEY: It sounds like a lot of times, though, VSAC will catch them and have them change the VSAC application.

COMMITTEE MEMBER LUND: Yeah.

VICE CHAIR DICKEY: It's just the other case where it's the problem.

COMMITTEE MEMBER LUND: Yeah.

DR. RYKACZEWSKA: It's an upfront expectation so they know.

COMMITTEE MEMBER LUND: Yeah. Yeah. And, you

know, the thing, as Dr. Schaeuble was saying, consistency in dates, you know, this is one of the things that I see when I go back and forth. It's like, you know, is it until 2017 is the end date or 2019. They sometimes don't fully describe on one side or the other in the procedures section. You know, sometimes the description in the VSAC procedures is a little different description than in the CPHS protocol.

So, those are the kinds of things that, you know, now when I do my comparison I see. So just, you know, a heads up to them that those are the things that need to be the same across the two applications. Just a suggestion.

COMMITTEE MEMBER SCHAEUBLE: And very often different variables even.

COMMITTEE MEMBER LUND: Yes.

DR. RYKACZEWSKA: That dates, variables, procedures description that's common.

Okay, other thoughts? Other comments.

VICE CHAIR DICKEY: There's more to do with VSAC?

DR. RYKACZEWSKA: Hum?

VICE CHAIR DICKEY: There's more to do with VSAC?

DR. RYKACZEWSKA: Yes, there is.

So, we did include the draft letters of support that CDPH has created in case there's any feedback on those. So, there are three.

One is the kind of general letter of support for

most applications. One is specific to the death data-only applications. And then there is a continuing application, so when there are amendments that would be there.

Is that correct? Just double checking that I interpreted all three correctly. There is a general, a death data-only, and a continuing.

COMMITTEE MEMBER SCHAEUBLE: Well, being a nitpicker, I have a language issue with one place in the letters. The last sentence of the first paragraph, because that sentence begins with the phrase, "if the proposed use of data has been modified", would make it sound like the end of the sentence, "release of the information would be in compliance with state laws", is connected somehow to that "if" statement at the beginning. Which I don't think is what's intended.

So, it seems to me the word "and" should be removed and the last part should be a separate sentence, "any release of information" as a separate sentence on all three letters.

DR. RYKACZEWSKA: Recognizing I'm not sharing that document, just to make sure. Just one moment. There can only be challenges, but I want to make sure that I am capturing the right spot. Well, it's here somewhere.

VICE CHAIR DICKEY: Is that it?

DR. RYKACZEWSKA: So, this is the letter. And so,

what I am hearing, Dr. Schaeuble, you say is that there should be a period --

COMMITTEE MEMBER SCHAEUBLE: A period after "required" and --

DR. RYKACZEWSKA: And that this is an independent statement of any cause, "any release of information pertaining to this project will be in compliance with applicable state laws."

COMMITTEE MEMBER SCHAEUBLE: Yes.

DR. RYKACZEWSKA: Any concerns from CDPH on those changes?

DR. ENDOW-MONTEIRO: That looks like a good change to me.

VICE CHAIR DICKEY: That was not nitpicking.

(Laughing)

MS. MILES: I'm good with that change.

DR. RYKACZEWSKA: Sorry, Michelle?

MS. MILES: I'm good with that change.

DR. RYKACZEWSKA: Any other feedback?

Not hearing any. All right, so then the last piece on this agenda item that we wanted to talk through was a little bit around the five-year rule. So, a little bit of context, because we realized that a lot of our confusion may have been stemming from terminology that we use that's very similar, but meaning very different things.

So, CPHS has what we call a continuing review that happens on an annual basis. That is essentially checking in with the researcher saying, hey, how are things going, are there any changes that you haven't let us know about, and any adverse events. So, that's essentially an annual check in, is the research still adhering to the protocol that has been approved. And what are you plans for the next year. That's some of the things that we review as part of the continuing review.

CDPH does not institute a separate annual review. Instead CPHS, when we do our annual review we send our approval letter to the CDPH to let them know, yes, we've done it, it's approved for another year.

Instead, CDPH does have what they call a continuing application. But that's more akin, from my understanding, and again Michelle, Joshua, please correct me, but that's more akin to what we call an amendment.

So, if there's a change, the researcher, to CDPH, submits a continuing application.

And so, just wanted to first start with that distinction because the terminology was really confusing, and we talked about it with each other I think a couple times.

And then, I'm going to try to describe the five-year rule. And oh, I see, Michelle, your hand up.

MS. MILES: Yeah. Before you move forward, we've been kind of having internal conversations about that issue about the language. And we're looking into seeing if we can change our continuing application to an amendment. So, that we kind of align with your terminology.

So, hopefully in the future our language will be the same not so confusing.

DR. RYKACZEWSKA: Thank you, Michelle, that's helpful.

So, I'm going to try to explain what I understand the five-year rule to be. CDPH, please correct me because I know we've had some back and forth on this one.

So, when researchers need data beyond what is currently available from CDPH. So, let's say right now 2023 data is available, but they're recognizing they're going to need additional years of data. They can request up to five years of data beyond what is currently available.

I'm going to pause for a second just so any -- okay. So, they can request up to five years of data beyond what is currently available before they would need to submit a continuing application, or what will probably be called an amendment in the future, to CDPH.

So, to give a little bit of an example of this, if a researcher today submits an application that request 2023 data, because that's what's available right now, they can

additionally, when the time comes, request 2024, 2025, 2026, 2027 and 2028 as those become available, without needing to go back to CDPH. I think.

I'm seeing some shaking --

MS. MILES: Yes. Yes, let me stop you.

DR. RYKACZEWSKA: Yes, please.

MS. MILES: So, in their initial application they are able to request five future years of data. They don't have to come back to us every year. So, their initial request would request 2023 data, because that's what's available, and five years out into the future. So, that initial request is requesting 2023 through 2028.

COMMITTEE MEMBER LUND: So, I --

DR. ENDOW-MONTEIRO: But we also do not deliver the data unless they have an approval, a non-expired approval from CPHS. If their approval expires, we will not be delivering the data.

MS. MILES: Correct.

COMMITTEE MEMBER LUND: So, if I could provide some background on this.

DR. RYKACZEWSKA: Uh-hum.

COMMITTEE MEMBER LUND: Dr. Dickey and I are responsible for the five-year rule.

VICE CHAIR DICKEY: Oh, wait, I --

(Laughter)

COMMITTEE MEMBER LUND: Because we initiated this discussion with the board, it's been a few years now. We had an application for Vital Records data that wanted a 20-year end date. And we were very uncomfortable approving a study for 20 years because at that time we'd had several adverse events in a row involving Vital Records data for long-term studies, where the PI changes, and the PI is not made aware of the rules of, you know, the data, especially the data sharing of Vital Records data and other aspects of Vital Records data.

So, we had proposed to this Committee that five years seemed like a reasonable time for a researcher to have to go back to CDPH and have their project reapproved before we approve the continuing review, annual review.

Because laws can change, PIs can change and not be aware at all of what the rules are surrounding the data. And they might be, as we found with a couple of adverse events, doing things with the data that they're not allowed to do. Which, if they had had to go reapply to CDPH, they would have found out in the new data sharing agreement that, no, we can't do that with our data.

So, that was the origin of this five-year rule. And we actually had discussed it as a board and everybody agreed with the logic behind that.

I'll be the first to say it has been troublesome

in its implementation, especially for staff. And if there's a better way to do it or modifications of the current way, I just -- I want to express that I still have that concern about approving long-term projects because of the number of adverse events associated with these long-term projects that never have to go back.

VICE CHAIR DICKEY: Since you brought me up --

(Laughter)

VICE CHAIR DICKEY: Yeah, also, I don't think we understood that what -- we were having trouble getting CDPH to review these. We were saying you've got to back and apply to CDPH because it's been over -- or five years, but it may not have fit their rules in terms of when they wanted them to come back.

So, we just wanted to get this so that we're in sync, so we're not sending people back that they said, well, we don't need to see this.

COMMITTEE MEMBER LUND: Yeah, right.

DR. RYKACZEWSKA: Right. And I think you also -- Laura, you brought up a really good point that that was a distinction that we were starting to make in our conversations, as well, of there's the how many years of data you can request into the future, and then there's the how long do you get to keep this data, which would be based off of the end date of the project.

And so, I'm going to kind of skip ahead a little bit but, hopefully, it will make sense. There are a couple of things that we're recommending. So, we're not wanting to necessarily change any of the rules but, rather, in terms of how we think about implementing them.

So, one piece, one recommendation that I have is for us, for CPHS, we've been checking the VSAC letter of -- sorry, approval letters during the continuing reviews, and we've been waiting five years.

Based off of the fact that this is about five years of additional for CDPH, my recommendation would be to move that to the amendment. So, when researchers want to add additional years of data they have to submit an amendment to us. And so, I think that would be the moment where we check to say, well, did they actually already receive approval from CDPH to have that additional year or have they passed the initial five years. Because oftentimes researchers will submit an amendment to us on an annual basis saying, okay, this data is now requested.

And so, we fell like that would be to meet, to align in terms of how CDPH has been describing it. We would check that at the amendment process when the researcher is asking for additional data.

And, and in the CDPH approval letters, they're proposing to add an expiration date to those letters, so

that we also know when's the end date or when's kind of the moment we need to be double checking to help support our team in terms of what's the date that we should be looking at.

COMMITTEE MEMBER LUND: So, how would you handle the situation where there are annual continuing reviews, but no request for additional years of data? Because that's where we would run into a lot of trouble.

DR. RYKACZEWSKA: So there, I think that what we're wanting to make sure is aligned is the end date of the project. So that what CDPH has in their system as this is the project end date matches ours. Because through our continuing reviews we can always add an additional year, the researcher can add an additional year to their end date. And we're wanting to make sure that that's aligned with that expiration date so that the two systems have the same end date in place.

COMMITTEE MEMBER LUND: Okay.

VICE CHAIR DICKEY: And it's my understanding that to extend the end date with VSAC or with CDPH, they just have to go into the portal, that CDPH has, extend the end date. They don't have to go back other than that, it's sort of an automatic thing.

COMMITTEE MEMBER LUND: And that creates a problem because then, once again, nobody is actually reviewing this

to make sure --

DR. RYKACZEWSKA: Well, I'm --

VICE CHAIR DICKEY: Let's ask them.

COMMITTEE MEMBER LUND: You know, I don't want people to be able to do this for 20 years.

DR. RYKACZEWSKA: Michelle, I --

MS. MILES: No. Laura, can I interject? So, what we are talking about is we are -- we are talking about actually putting in a five-year expiration date into our system. And if CPHS gets an amendment between that period of time, we are requesting that you make sure that you push them back, that researcher back to us to ensure that we have the correct information for that project.

COMMITTEE MEMBER LUND: And would that apply to continuing reviews as well, and not just to amendments?

MS. MILES: I'm sorry, say that again?

COMMITTEE MEMBER LUND: Would that apply to continuing reviews as well, and not just amendments? Because continuing reviews don't require an amendment.

MS. MILES: What I'm understanding is a continuing review is just an annual review that where they could possibly be requesting an additional year of date. Is that correct?

DR. RYKACZEWSKA: No. No.

COMMITTEE MEMBER LUND: No, no, no. No, a

continuing reviewing doesn't require them to request anything additional. This Committee looks at the project every year. And so, they can apply to say we want to continue our project for the next year.

And my concern is that those will be missed, and we will approving these continuing reviews. Because I understand if they apply for amendment how you're planning to kick that back to your system, and compare end dates, and so forth, and that's great.

My concern is with the continuing reviews that don't get any other scrutiny.

DR. RYKACZEWSKA: And in the continuing review they can request an extension of the --

MS. MILES: So, when you do your continuing review you provide an additional -- another year worth of data that they can use?

VICE CHAIR DICKEY: No, not data.

COMMITTEE MEMBER LUND: No, no, not data. It just keeps the project alive, it doesn't -- there's no new data. The project is as is, but they have approval for another year beyond the date that they had original proposed to end it.

VICE CHAIR DICKEY: It's --

DR. RYKACZEWSKA: Yeah, so the continuing --

MS. MILES: And our system does capture that new

expiration date. We are running reports monthly to ensure that our applicants have a valid expiration date with CPHS.

VICE CHAIR DICKEY: So, how do you get that information? Is it -- don't they have to go back into your system and say, I want another year?

MS. MILES: Yes.

VICE CHAIR DICKEY: So, it's relying on them going into your system and informing you.

MS. MILES: But if we -- we're running these reports and if they don't have a -- if their expiration date is coming due, we have emails that go out to that researcher that tell them that they need to be putting in a valid expiration date.

COMMITTEE MEMBER LUND: And if --

MS. MILES: And attaching that at that -- approval letter into the application, their application.

DR. RYKACZEWSKA: And I see a hand from Joshua.

DR. ENDOW-MONTEIRO: And I think we did this as an archive, and maybe that's where some of the confusion is. Because that's we are already checking -- if there's an amendment, it goes to us. If there's an additional year -- additional years requested, they will need to submit what we call a continuing application. They will need to submit an application to us for approval to request additional years of data. They will not be -- they will not receive any

additional years of data. So, I think that's already built into the current process.

But we did like the proposal that you would review during the continuing review, because that happens every year. And that would -- that would be the best way to capture if they haven't -- if we haven't seen their application for five years, you would pass that at that time.

And I think in our internal discussions that seems to be the best way to implement this and would be a way that we would at least have projects checked in on us, on a regular basis.

VICE CHAIR DICKEY: I'm not quite sure what the process is there.

COMMITTEE MEMBER LUND: Yes.

DR. RYKACZEWSKA: What I'm starting to hear and totally open to this, is the (indiscernible) -- so, when we do the continuing reviews and the researcher is asking to extend the end date of the project by a year that we check that that end date is consistent with what they -- or that they're updating it with CDPH, or that it's consistent with what they put in with CDPH.

VICE CHAIR DICKEY: How do we --

DR. RYKACZEWSKA: And --

VICE CHAIR DICKEY: -- how do we check that,

though, as a reviewer? I mean, we can say we're giving you an expert year and you need to update this with CDPH, but we don't have access to their system to check what their end date is.

DR. RYKACZEWSKA: And I think this is where the expiration date, the new expiration on their approval letter comes in is, is that expiration date aligned with what they're saying the end date of the project will be.

Is that Joshua -- I'm seeing at least a nod from you.

DR. ENDOW-MONTEIRO: Yes, yes, yes --

COMMITTEE MEMBER LUND: I still don't know how we'll know. As a reviewer I'm sitting there, do I approve it, and if I approve it will it go beyond the five years, right, because --

VICE CHAIR DICKEY: Right, right, you don't know.

COMMITTEE MEMBER LUND: Yeah.

DR. RYKACZEWSKA: Well, the expiration date would be based off of the five years.

VICE CHAIR DICKEY: But if it's in the letter, but then we get it at year six we say, okay, we'll give you another year, how do we know that they're going to inform CDPH about that.

DR. RYKACZEWSKA: Would CDPH release a new letter with a new expiration date, once the expiration is reached?

Or, could that be a way to do it? So that we, essentially, once the expiration date has changed --

COMMITTEE MEMBER LUND: I'm looking at a continuing review form in IRBManager.

DR. RYKACZEWSKA: Uh-hum.

COMMITTEE MEMBER LUND: How do I know what the expiration date is so that I'll know they're at their five years.

VICE CHAIR DICKEY: There is an expiration --

DR. RYKACZEWSKA: CDPH would include it in their approval letter. So, when we have the approval letter from CDPH we would look for expiration date on that approval letter.

VICE CHAIR DICKEY: But that doesn't get entered into IRBManager, though,

DR. RYKACZEWSKA: The approval letter?

COMMITTEE MEMBER LUND: And it doesn't show for me on my continuing review form.

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER LUND: Right? So, there's no way for me as a reviewer to know, and I'm being asked, oh, we want to extend our project a year and how do I know to say no?

DR. RYKACZEWSKA: Could we add the -- in our continuing review applications, add a spot for them to

attach the approval letter I think might be the best, the best way to do it.

COMMITTEE MEMBER LUND: Or just maybe a question, did your data expire?

COMMITTEE MEMBER SCHAEUBLE: Could we have, in IRBManager, a place that shows not only the expiration date that CPHS is working with, but also the one that comes from the CDPH approval letter as a separate item, so that they would be together for us to see at the same time?

COMMITTEE MEMBER LUND: Yeah, just a question that says what's the expiration date on your CDPH approval letter? And that way --

COMMITTEE MEMBER HESS: Or can we just have a spot on IRBManager where for continuing review they have to upload their approval letter.

VICE CHAIR DICKEY: Their original letter?

COMMITTEE MEMBER HESS: Their original approval letter, and then we have it, and we don't have to ask them.

COMMITTEE MEMBER LUND: Yeah.

COMMITTEE MEMBER SCHAEUBLE: I think it would be better if that CDPH expiration date could captured as a data item that is stored in the IRBManager application, rather than simply asking the researcher for a response, or trying to locate an approval letter somewhere that --

COMMITTEE MEMBER LUND: I mean, there could even

be a nifty little bit of programming that says, oh, you're asking for a date that's past your expiration. You have to go back to reapply to CDPH or something like that.

VICE CHAIR DICKEY: I guess my question comes down to who enforces this? And if -- could they, on their end, catch this? And I know they send out reminder letters, your project is expiring. And if they don't come back with a reply, then they stop the researcher as opposed to us trying to --

COMMITTEE MEMBER LUND: How will we know?

VICE CHAIR DICKEY: We won't know that. I mean, I'm just saying they're the ones who are -- it's their data and they're sending out the letter saying you need to extend your project. And if they don't get a response, then they would stop it, right.

COMMITTEE MEMBER LUND: Yeah.

VICE CHAIR DICKEY: I guess this is a question to them?

MS. MILES: Yes, we do -- if we don't get a response from them, we then contact them and -- we either, one, don't deliver any additional data to them with an email that says you need to destroy the data you have on hand. You should no longer be utilizing it until you get, you know, a valid approval letter through the CPHS.

So, we do contact them. We do stop, cease

delivery of data and let them know they need to stop using the data on hand until, you know, we have valid expiration dates.

DR. RYKACZEWSKA: And can confirm because that actually just happened in the last month. There was a continuing review that went past this date and there was -- the researcher did let us know that, like, they received the letter from CDPH that they needed to destroy the data or get approval from CPHS. So, can confirm that at least once that's what happened.

COMMITTEE MEMBER LUND: Yeah. I'm just concerned, based on real-life experience here with a couple of projects, sometimes PIs change. Sometimes people don't get your email because there's a new PI and the new PI doesn't know the rules. I mean, this is an actual thing that's happened.

So, how -- for us, how do we ensure when these -- I just want to know how do we ensure when the continuing review comes through for us that it's okay to approve it for another year, or we've hit the five-year mark and we need to tell them they have to go back to CDPH?

DR. RYKACZEWSKA: So, with the change of PI, that would have to -- that can't occur, from my understanding, in a continuing review. That has to --

COMMITTEE MEMBER LUND: That's not what I'm

saying. That's not what I'm saying. They change PIs and they don't tell CDPH. They tell us because there's an amendment and there's a new PI, but they don't always tell CDPH. So, CDPH may not have, and especially I'm thinking about these long-term projects, once again.

So, I just want to know how we, in IRBManager, they've come through and they've said, oh, yeah, another year, no adverse events, whatever. How do we know that we can approve that for another year, and it hasn't gone beyond the five-year mark?

VICE CHAIR DICKEY: They have the end date. That's the problem, we don't have it.

COMMITTEE MEMBER LUND: Yeah. I think --

VICE CHAIR DICKEY: But the change of the PI, shouldn't that be an amendment?

COMMITTEE MEMBER LUND: It's an amendment for us. I'm saying that --

VICE CHAIR DICKEY: But we're saying any amendments that we approve have to be -- they have to have submitted an amendment to them, also.

COMMITTEE MEMBER LUND: It has not always happened in the past. There have been many changes in personnel that CDPH has not been aware of, which is why we've had adverse events.

DR. RYKACZEWSKA: Okay. I'm going to say I think

this is the place where we need to work some more, and do some more thinking, and exploration.

And just in the interest of time, because I know we are trying to get to the next agenda item, what I would recommend, then, is for our CPHS admin team to keep working with CDPH on this five-year rule and thinking through how we might implement this.

COMMITTEE MEMBER LUND: And I'm happy with the suggestions that were made. I've heard two. One is to actually be able to have the person who's applying for the continuing review enter the expiration date from the letter, or attach the letter so that we, ourselves, can confirm it. And that applies to us.

Regardless of what's happening on the CDPH side, that provides us, as reviewers, with assurance that we're acting responsibly in approving for another year.

DR. RYKACZEWSKA: Uh-hum. And I think, so, that's for me to confirm with the IRGC Manager vendor to see whether we can add that and how hard that would be.

I think it's a good suggestion and I really like it, too. I just want to confirm that it's feasible. And then, to really make sure we have an understanding of how the expiration date will be determined from CDPH's side, so that we really have an understanding of what that means in the letter.

COMMITTEE MEMBER LUND: And just to be clear because I think, I know you're trying to move it on, I just want to say one more thing. And just to be clear, so CDPH understands, these are not amendment situations. Because Joshua's correct, when there's an amendment, they see the amendment, so we're in sync on the amendment. It's these continuing reviews that are not asking for changes or for additional years of data, because we don't do that through continuing review. We do that through the amendment process. These are very specifically continuing reviews, what we call continuing reviews.

DR. RYKACZEWSKA: Okay.

VICE CHAIR DICKEY: It's like how long can they hold onto the data, basically.

COMMITTEE MEMBER LUND: Yeah.

COMMITTEE MEMBER HESS: There was a question in chat from someone about destruction of data.

DR. RYKACZEWSKA: Oh, I'm sorry. I am not seeing any questions in the chat.

COMMITTEE MEMBER HESS: Oh. I saw a question pop up, "how can we be assured, how does CPHS know the data has been destroyed?"

DR. RYKACZEWSKA: Is there --

COMMITTEE MEMBER HESS: I'm literally the only one that saw it.

(Laughter)

COMMITTEE MEMBER LUND: So, we have a closure form that has to be approved, where they tell us if they've done that.

VICE CHAIR DICKEY: But actually, Sussan was working on a -- and I guess we'll get to this in the future, some criteria for the destruction that we might want to make it more specific than what we have in the closure form right now.

DR. RYKACZEWSKA: I'm curious from CDPH's side what -- what is your process for ensuring that the data did get destroyed? Is there something that researchers have to submit to you? Sorry. Slightly different topic.

MS. MILES: At this point there is not. We are trying to come up with something in IRBManager where they're -- where they are acknowledging that it's been destroyed, so that we can document it better.

So, unfortunately, we haven't gotten to that point, yet.

VICE CHAIR DICKEY: Well, this is an example where we might want to work together on that so that the criteria we have are the same as they have.

COMMITTEE MEMBER LUND: Is this my fault, Sussan, because I come back with all of those questions about there was destruction.

MS. ATIFEH: Actually, I was inspired with your comments, and I have all of your comments, and Dr. Schaeuble's comments help me a lot to create that checklist.

COMMITTEE MEMBER LUND: Okay.

MS. ATIFEH: Yeah, it was very helpful, and I was trying to find a good opportunity to thank you, and I really appreciate your careful comment.

INTERIM CHAIR DELGADO: So, I think more work for us to do, but this has been really helpful in terms of really understanding, you know, what's important. What do we make sure that we need to address through these processes. And I really do appreciate it.

So, Michelle, Joshua, I'll be reaching out to you after the meeting to continue our discussions and try to bring forth the refinements to the Committee, and new ideas with this input in mind.

MS. MILES: Yeah, we look forward to the continued communication because I think it's helpful for both sides.

DR. RYKACZEWSKA: Absolutely.

DR. ENDOW-MONTEIRO: Thank you all for your help.

INTERIM CHAIR DELGADO: Thank you so much.

Any public comments on this item? Not seeing any virtually. Any public comments, Nick, in the room.

MR. ZADROZNA: No public comments in the room.

INTERIM CHAIR DELGADO: Thank you.

MR. WHITE: Can I make a quick -- I have a quick, it's really a question, actually. This is Evan White, from University of California.

At one point there was talk of a common application that would sort of try and combine some of the aspects of the CDPH and CPHS applications, as well as some of the other applications within CHHS. I was curious whether there was any progress on that or any update on that.

DR. RYKACZEWSKA: Thanks. So, I can address that a little bit. So, we are still working on the common application. In terms of where we are is that we've worked with five different so far to try to identify what questions they has of researchers and combine them into a common questions, and then department-specific questions.

And we've been working on a common data use agreement, as well. And then, the CPHS pieces.

And, of course, there is a lot of interdependencies in terms of the CPHS piece of this with a lot of the conversations we've been having around the Common Rule and the IPA.

And so, we're really wanting to understanding where things are headed in terms of that before we really move forward with any sort of common application, so that it can really reflect the latest and greatest thinking in terms

of protection of human subjects.

So, it is still in the works. It is moving a little bit slower than I think we anticipated, but really wanting to make sure that it reflects current processes. So, stay tuned, there will be more but as we get more clarity around the Common Rule and IPA.

MR. WHITE: Thanks so much.

DR. RYKACZEWSKA: Uh-hum. Any other public comments or comments in the room?

I'm not hearing any. Okay.

(Whereupon, the Court Reporter asks for a brief recess to change batteries.)

(Whereupon, the Chair calls for a 10-minute break.)

(Off the record at 10:00 a.m.)

(On the record at 10:07 a.m.)

DR. RYKACZEWSKA: Thank you. All right, I think we're going to go ahead and come back, and begin our discussion of Item D, if that's all right. I'm slightly going slow in case there's any stragglers that need to get back.

(Laughter)

DR. RYKACZEWSKA: All right, going once, going twice.

So, the next item is another item where we're

really looking for feedback, your thoughts. And I'll be the first to say I'm sure we missed things, and so really looking for your thoughts on how we can improve this.

And this is a draft decision tree. So, just to set the context a little bit. We have been starting to experience some challenges in terms of the admin team really understanding what's the review types that we're doing. We're getting some questions from researchers around guidance. And, of course, over the last few meetings we've been having a lot of discussion, as well. And so, around the idea when does the IPA apply, when does the Common Rule apply, and all of those types of pieces.

And the intention behind this flow chart is just to create a simple tool that can be useful to us, to Committee members, to researchers to understand which laws apply and when.

Now, I also recognize that we're still having many of these IPA and Common Rule discussions, and their subcommittee is still meeting around the draft regulations.

And so, my intention was, when I was trying to create this, is to make this independent of what the subcommittee is still working on. So, in the sense of recognizing that the subcommittee is proposing what criteria CPHS applies when the IPA is -- when it's doing its review under the purview of the IPA.

Where this flow chart is trying to determine, well, when does the IPA apply. And so --

VICE CHAIR DICKEY: And when does the Common Rule.

DR. RYKACZEWSKA: And when does the Common Rule, yeah.

And so, my hope is that this flow chart will be something that can stand moving forward.

And so, I worked very closely with Maggie to really try to take a look, it's based off our discussions, thinking of some of the memos and things that have been put forth, really to try to create as simple of a reference tool as I could, recognizing this is a very nuanced discussion.

So, I think I'll try to walk through the flow chart, highlight some of the things that kind of just maybe a little bit different from how the previous decision tree was organized, and then open it up for your questions, feedback, thoughts.

So, with that let me actually pull it up. There we go. This one. Sorry. All right, and share the screen, and here we go.

Okay. So, I recognize you can't read anything on here. But I will zoom in, in a moment. And this is also in our packets. And there's two versions printed in our packet, one that's the zoomed-out version like we have right now, and ones that you can actually read. So, we do have

access to both.

So, one of the things that I want to point out in this zoomed out version is that recognizing that these are two separate laws that are independent of each other, and they don't reference other, one of the things that we did as we organized this was to separate them out into two questions that have to be answered to actually determine which apply.

And then, recognizing and hearing from many of the Committee members in the past meetings, sometimes studies can fall under both. It's not an either/or sometimes. And so, this box at the bottom kind of helps address that piece where it kind of walks through, okay, if you answered yes to this, but no to that, if you answered yes and yes to kind of point that out that it can be both.

And so, I'm going to go ahead and zoom in and start walking through it. But please feel free to stop me at any time.

So, question one has to do with the Common Rule. Does CalHHS, CPHS have purview under the Common Rule. And to get to a decision on that, there's a series of questions that we have to answer.

So, the first question is, is this even a research study or, as Dr. Dickey mentioned in the previous item, is this a marketing where they're trying to, you know, market

tombstones, right. So, it's the first thing that we need to determine is, is this research per the federal regulations.

And so, we did try to include some comments here, just as quick reference materials. So, as defined, research is considered to be a systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge. That's kind of the definition of research. And so, to answer this question we have to think of that definition.

I'm kind of debating on this, but we wanted to give an example of something that might not be typically considered research, so we pulled actually the Public Health surveillance activity definitions to give kind of a contrasting example, and that's what below that. To just give an example of what constitutes not research, but public health surveillance.

And I will go ahead and note we have received already one comment that I want to call out, to add -- if we're going to include those, to add that for research that started for 2018 this criteria might not apply.

COMMITTEE MEMBER LUND: And we might also say that this is an example. Because my question was going to be, before you said that, how come you specifically have public health here as an exempt activity, but there is a whole list of other ones, educational, and so on and so forth.

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: It might be helpful, just a suggestion, if you say there are examples and have an addendum document, so what might constitute examples that are not research. Just so people have an idea because the list is actually very --

VICE CHAIR DICKEY: Well, I think the bottom box deals with those, those exemptions.

COMMITTEE MEMBER LUND: Okay.

VICE CHAIR DICKEY: But there's certain things that are considered to be not research up front. And probably the biggest one would be program evaluation.

COMMITTEE MEMBER LUND: Yeah.

VICE CHAIR DICKEY: Where they're only going to use the information to improve their own program, they're not going to create generalizable knowledge.

COMMITTEE MEMBER LUND: Yeah, and the public health surveillance is not to create generalizable --

VICE CHAIR DICKEY: Public Health Surveillance, also.

DR. RYKACZEWSKA: Okay, we can definitely do that. Okay.

So, that's question one. If the answer to that is, yes, it is research, it is for generalizable knowledge, then we have to ask, well, is it human subjects research, is

it research involving human subjects.

And so, this is -- I mean, I think we discussed this at the March meeting, the definition here or the guidance here about what constitutes human subjects research. So, if they're obtaining, for the purpose of research, information or biospecimens for intervention or interaction, or if they obtain, use, study, analyze private identifiable information. So, is it human subjects research is the next question.

If it's -- uh-hum?

COMMITTEE MEMBER LUND: Just before you move on I want to say thank you very much because I think you've captured both the interacting with human subjects and the use of secondary data sources, which are both under Title 45. And this has been my objection all along is to calling things data-only studies and putting them in the IPA bin, when in fact the data-only studies that are subject to the Common Rule fall under B here. So, much appreciation and thank you because I think that clarifies a lot of points.

DR. RYKACZEWSKA: Okay.

VICE CHAIR DICKEY: But the operative word in here is "obtains". So, that's, this is where we've gone back and forth. Releasing data.

DR. RYKACZEWSKA: Right, right, right, right.

VICE CHAIR DICKEY: If you're obtaining it, then

you are basically engaged in human subjects research.

COMMITTEE MEMBER LUND: Yes, no argument.

DR. RYKACZEWSKA: So, if the answer is no, it's not human subjects research, which very rarely ever happens in any of our applications, that would mean it's not under the Common Rule. But the vast majority, if not all of our applications will meet this definition of human subjects research.

So, they would continue down to the next question, which is I think --

VICE CHAIR DICKEY: Well, I --

DR. RYKACZEWSKA: Uh-hum?

VICE CHAIR DICKEY: I just want to differ with that because the IPA requests, I mean we get a lot of those, are not human subjects research.

DR. RYKACZEWSKA: I think this is where the --

VICE CHAIR DICKEY: Well, wait, I mean IPA only.

COMMITTEE MEMBER LUND: She's getting there.

DR. RYKACZEWSKA: I think we are getting there.

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: So, I think this is where that question comes in of it might be human subjects research for that researchers --

VICE CHAIR DICKEY: And for their IRB.

DR. RYKACZEWSKA: -- and the question is, is

CalHHS engaged in the research. Because that, I think, is the core of what we've been discussing over the last few months.

VICE CHAIR DICKEY: Right.

DR. RYKACZEWSKA: And so, included, this box here, in terms of the OHRP guidance, of what does it mean to be engaged in human subjects research.

So, that means that the institutions, employees or agents, for the purposes of research obtain data about the subject through intervention or interaction, obtain identifiable private information or obtain informed consents of the research subjects.

And to your point, Dr. Dickey, there is a point made at the bottom here that if the institution is releasing, solely releasing the information that falls under the human subjects definition, rather than doing the things that are above.

VICE CHAIR DICKEY: Right.

DR. RYKACZEWSKA: Then that releasing institution is not required to review and approve under the Common Rule.

VICE CHAIR DICKEY: Right.

DR. RYKACZEWSKA: So, that distinction about are we engaging in that research, is CalHHS engaging in that research --

VICE CHAIR DICKEY: Right.

DR. RYKACZEWSKA: -- or are we just releasing is the intention of the question.

VICE CHAIR DICKEY: Yeah, I see your point. So, virtually all our projects are human subjects research, it's just we're not necessarily engaged in it.

DR. RYKACZEWSKA: That's, I think that's a distinction.

So, that is -- that is that question. Any -- I'm going to pause here, because I know this is where a lot of the discussion has been, just to make sure --

COMMITTEE MEMBER LUND: Just, I just want to clarify, and maybe it's on a box that's further down, engaged means performing the research, funding the research, providing other resources such as staff to be engaged in the research? Yes? I'm looking at our attorney.

VICE CHAIR DICKEY: Well, I think you'll find that what it says in the Common Rule and what we have differs.

MR. GOLDMAN: That's true. So, funding is not engagement in this.

COMMITTEE MEMBER LUND: So, if one of our agency departments is funding a research study, we do not have Common Rule purview as the board over that research study?

MR. GOLDMAN: Correct.

COMMITTEE MEMBER LUND: Really?

MR. GOLDMAN: Really.

COMMITTEE MEMBER LUND: Wow, okay.

VICE CHAIR DICKEY: Not officially under the Common Rule.

MR. GOLDMAN: Correct. It wouldn't prevent a department from requesting an IRB review. I mean, remember that departments control their own information and if they want an IRB level of review, they can ask for it.

COMMITTEE MEMBER LUND: This is why we review the California Health Interview Survey is the department's funded, but we're not engaged in the --

VICE CHAIR DICKEY: I understand.

COMMITTEE MEMBER LUND: Okay. But I'm pointing at you because it's your study.

VICE CHAIR DICKEY: I think the discussion would show us there's sort of a disjunction between the Common Rule and what we actually do.

COMMITTEE MEMBER LUND: Okay. All right, thank you for the clarification. I just wanted to make sure I understood.

COMMITTEE MEMBER HESS: But then, how -- how do -- wait, okay, I'm going to circle back then. How is -- like we do fund California Health Interview, but like I am at CDPH and I'm actually involved in the design of the questions. Yes.

VICE CHAIR DICKEY: Well, then that would be --

that would be engagement.

COMMITTEE MEMBER HESS: Yeah, and so I think there's very often funding seed, departments that fund studies are actually engaged. Because when we review the survey --

VICE CHAIR DICKEY: Exactly.

COMMITTEE MEMBER HESS: -- is to review the protocol. That means they're engaged in --

COMMITTEE MEMBER LUND: If staff, if state staff are involved in the work.

COMMITTEE MEMBER HESS: If staff are involved.

COMMITTEE MEMBER LUND: And I'm looking at Jared.

MR. GOLDMAN: Yes.

COMMITTEE MEMBER LUND: So, that is okay. All right.

COMMITTEE MEMBER HESS: So, that -- I mean, that's most state-funded projects, though, would have some level of involvement by staff staff in the project, so --

VICE CHAIR DICKEY: So, if state staff oversees the contract that is funding the project, could that just be considered engagement?

MR. GOLDMAN: Not necessarily. I mean, and this is also -- I would say these are all fact-specific, and so I prefer not to --

(Laughter)

MR. GOLDMAN: -- not to make broad generalities about any particular contract. I mean, I'm not going to broadly say just because we have a contract with someone that we're engaged in research.

VICE CHAIR DICKEY: Okay.

COMMITTEE MEMBER LUND: Okay. So, that's --

INTERIM CHAIR DELGADO: But it is a distinction. Like someone who is executing, a grants manager who is executing a contract has very different activities than a staff member who's helping develop the questions or review iterations of findings, and editing said findings.

COMMITTEE MEMBER HESS: Yeah, and I think there could be a loophole that some departments try to exploit there, where they're saying, well, we're just funding the research but, say, this UC is doing the research, without really being honest about the level of involvement of the actual department in the research.

So, I don't know that that distinction should be made in writing, like what constitutes engagement on behalf of a CHHS department.

COMMITTEE MEMBER LUND: So, do you think, and this might be -- just give me a little latitude to try and dive into the details just a little bit. So, it might be the case that when we ask them to list the research staff involved that if there's anybody with a department email,

that we would consider that that department is engaged in the research, as opposed to just having a contract manager be involved, because they wouldn't be listed as part of the research team?

MR. GOLDMAN: What I would suggest we do, maybe, is include a link to the OHRP guidance which defines engagement, and then people can look at the actual rule, rather than us trying to make it up.

COMMITTEE MEMBER LUND: Okay.

VICE CHAIR DICKEY: Yeah.

MR. GOLDMAN: Absolutely.

COMMITTEE MEMBER LUND: Thank you.

DR. RYKACZEWSKA: All right. So --

VICE CHAIR DICKEY: You're on a roll.

COMMITTEE MEMBER LUND: You're doing great, Agnieszka.

VICE CHAIR DICKEY: You're on a roll, you're on a roll. It's quite a roll, but --

DR. RYKACZEWSKA: No, but I think this is the conversations, really, that we hoped to have.

COMMITTEE MEMBER AZIZIAN: Oh --

DR. RYKACZEWSKA: Oh, do I -- Dr. Azizian.

COMMITTEE MEMBER AZIZIAN: Yeah, I'm sorry, I was unable to raise a virtual hand. If we could go back to the first box there, I just had a question about the general

knowledge in there.

I heard the comment about program evaluation and you say a department conducts some type of analysis of their patients, or population, but they do not mean to disseminate this information, it's meant for internal purposes. And that does not constitute research. That part is clear to me.

What happens if later on they decide that given that they have this finding, and it may be of general interest to the broader community and they want to present this in a conference or publish? Would that require them coming back and then submitting work that has been completed already, potentially analyzed, for us to review and approve? How does that work exactly.

VICE CHAIR DICKEY: So, the publication is not part of the standard for generalizable knowledge. I mean, it could be an indication that it's for generalizable knowledge, but just the fact that they're going to publish something doesn't, itself, make it research.

INTERIM CHAIR DELGADO: Where do you get that definition from? Because I have always been -- in the situation, and I'll just throw out my experience and, please, others opine and correct, that let's say a program evaluation -- I actually have one of these in my departments right now, where the -- an entity was contracted to do a

program evaluation and that was conducted. They asked me, do I need to do, get IRB approval for that. I said, no, it is strictly program evaluation.

Now, six months later, the researchers want to present findings at a conference and publish an article. That, to me, constitutes contributing to generalizable knowledge, and so that then they should do a -- like a data-only review because now they're taking said findings to contribute to the general scientific --

DR. RYKACZEWSKA: It's like secondary research at that point.

INTERIM CHAIR DELGADO: Like a secondary research project.

VICE CHAIR DICKEY: Yeah, we've never approved anything retroactive.

INTERIM CHAIR DELGADO: But we wouldn't be approving --

COMMITTEE MEMBER LUND: They can publish and share program evaluations --

VICE CHAIR DICKEY: Yeah, they can.

COMMITTEE MEMBER LUND: -- as long as it's still program evaluation. The idea is generalizable knowledge they would be -- if their intention was that they did this program evaluation, but it was --

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER LUND: -- generalizable to a whole bunch of other programs --

VICE CHAIR DICKEY: To all other programs.

COMMITTEE MEMBER LUND: But if it's just specific to that one program and the findings are specific to that program they can --

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: -- they can roll the publication.

VICE CHAIR DICKEY: Right. Right. But we have had people come back to us.

COMMITTEE MEMBER BAZZANO: Hey?

INTERIM CHAIR DELGADO: That's Alicia.

COMMITTEE MEMBER BAZZANO: This is Dr. Bazzano, yeah.

INTERIM CHAIR DELGADO: And then, I think Dr. Schaeuble.

COMMITTEE MEMBER BAZZANO: I think that that's quite a shift from my understanding as a researcher because I've been through this Committee several times for my previous program evaluations when we've presented, you know, and disseminated. I mean, when you are presenting at a conference, it is for disseminating knowledge with the expectation that it's going to be used as a --

VICE CHAIR DICKEY: Right.

COMMITTEE MEMBER BAZZANO: -- potentially as a model for other programs, or whether it's going to be published. I've gone through this Committee multiple times with secondary data that we've used exactly for this. And I think it would be quite a shift to say that this kind of secondary data analysis for presentation or for -- or for publication would not be considered research.

And also, I think you brought up a good point as to whether it's an internal research -- an internal program evaluation versus if it's a contracted-for-them evaluation, an then the contractors are disseminating it.

And then, I think -- I think this does make it a radical change and probably deserves quite a bit of thought. And, potentially, reviewing what other IRBs do. Because all the other IRBs that I know about, when you do decide that you want to publish these findings and, you know, that's why you want to publish it is for generalizable knowledge. But otherwise, everybody internally already knows. I mean, if it's an internal presentation, if you're at a hospital and you're presenting data because it's a quality improvement project for the hospital, and you want to make sure that the hospital knows so that they can, you know, work on it in that sense, or that you can present the data because you're -- you want to show the improvements, that's one thing.

But if you're presenting it out at a conference,

the purpose of being out at a conference, the purpose of being out at a conference, the purpose of publication is to be able to use that knowledge more broadly.

So, and from what I understand from other IRBs, you know, certainly you have to go through the IRB. It's an expedited process. It's not like you have to come to the IRB -- and it's not like you have to go back and get anybody else's, you know, permission. I've never seen or heard of an IRB making you go back and reconsent anybody. But it does go through the expedited processes. That's been my understanding.

INTERIM CHAIR DELGADO: That was my understanding.

COMMITTEE MEMBER BAZZANO: So, this is worthwhile, at least --

VICE CHAIR DICKEY: Could I -- I know I've talked a lot but --

COMMITTEE MEMBER BAZZANO: -- looking historically and then looking across. I think it's worth looking historically and then also looking across at other IRBs, to just see firsthand at others before making this change.

COMMITTEE MEMBER DINIS: There's also journals that won't accept publications without an IRB review.

DR. RYKACZEWSKA: Dr. Schaeuble?

COMMITTEE MEMBER SCHAEUBLE: Well, I agree with Darcy and Alicia. And, certainly, my understanding and I

think the general understanding is that presenting at a conference or publishing in a journal, at least in a circumstance other than some kind of a report that would only be internal to the organization doing the program review, that those other kinds of activities clearly are intended to add to the pool of generalizable knowledge and represent that kind of activity and, therefore, are considered research.

This creates a real quandary for the person who's planning and conducting a program evaluation because if they submit it as a program evaluation only, and it's reviewed only in that context, and they decide at a later time that they would like to present the results somewhere else that's not really, technically a legitimate thing for them to be doing because they haven't had the review for the process that would allow them to present in those other circumstances.

So, certainly the better judgment on their part and the better advice that we could offer, I think, is to say if you have any thoughts that you may want to present this information outside of your organization, you should be asking for a regular review, not simply a review limited to the program evaluation kind of a review.

DR. RYKACZEWSKA: Dr. Dickey?

VICE CHAIR DICKEY: So, I just want to lay out the

workflow on this, as I've been with this Committee, there is a form people can fill out asking it to be declared not research, and also a form to be declared exempt. And the decision, if they file a form that says we want to say this is not research because it's, you know, not generalizable knowledge or whatever, that decision is made by the Chair before those projects ever get to the Committee.

So, they have to specifically apply for it. If they just come in and file an application, we're just going to move it on to the Committee as a research project.

But if they say, they file a special form that says this is not research, that's something that traditionally the Chair has made the determination on before it ever gets to the Committee.

And this whole thing about what's generalizable, it's really a vague sort of thing. And if you look at OHRP's guidance, they say publication itself is not proof that something is generalizable.

So, it's really a judgment call kind of a thing.

COMMITTEE MEMBER LUND: So, I'm going to suggest maybe the language is in the regulation, Section 46.104, and that maybe we could review that.

VICE CHAIR DICKEY: Yeah, there is a form that we've created I think that has the language.

COMMITTEE MEMBER LUND: This may not be in the

interest of getting through just the basic work, the place to resolve it.

VICE CHAIR DICKEY: Right. We could get caught on every one of these rules things.

COMMITTEE MEMBER LUND: Yeah.

DR. RYKACZEWSKA: Yeah, I think I'm hearing two things. One, just even more to the point that an addendum that specifies all of the things that are examples of not research could be really useful here. And as part of that, really digging into program evaluation, what is generalizable knowledge and what guidance has been around that.

COMMITTEE MEMBER LUND: Very helpful.

DR. RYKACZEWSKA: Redoing that together.

VICE CHAIR DICKEY: Right.

DR. RYKACZEWSKA: Okay.

COMMITTEE MEMBER SCHAEUBLE: It certainly would be --

DR. RYKACZEWSKA: And I think -- and I do, not to go against what I just said three minutes ago, but I wonder if part of it is working at that sentence as like a full and complete sentence. I've oftentimes just looked at the piece that said when we then get to the part of contributing to generalizable knowledge it becomes research. But that -- like the first clause wouldn't be true. Like was it program

evaluation, a systematic investigation, kind of what you were saying. Like when you are presenting with a generalizable knowledge did it meet all aspects of that, all clauses of that?

VICE CHAIR DICKEY: And a lot of these things wouldn't be systematic. It could be we're just reporting --

DR. RYKACZEWSKA: Right.

VICE CHAIR DICKEY: -- how our program is doing, and that sort of thing.

COMMITTEE MEMBER SCHAEUBLE: It would certainly be helpful in this box if the second sentence began with something like an example of a situation that may be not considered research is.

VICE CHAIR DICKEY: Other than just public health.

COMMITTEE MEMBER SCHAEUBLE: Yeah.

DR. RYKACZEWSKA: Yes. Yeah, and that's what we're saying is rather than try and fit it into the box do an actual addendum that has several examples, and kind of digs into each of these things that are not research, but might seem like research, like Public Health Surveillance Program evaluation and those kinds of things.

COMMITTEE MEMBER SCHAEUBLE: But I'm also saying to call out that the points that are enumerated here describe a situation that may not be research, but depending on what the intention of the project coordinator is could,

in fact, be research.

COMMITTEE MEMBER LUND: And that's actually a good point. And specifically in the 2018 changes that was the thing that --

COMMITTEE MEMBER SCHAEUBLE: It was called out there, yes.

COMMITTEE MEMBER LUND: It was called out in the changes that two studies can look identical, but one might not be research based on the intention of the study. So, that's an important point.

VICE CHAIR DICKEY: Right. And they actually, when they were writing the 2018, they decided not just to say program evaluation itself is not research, although they considered it. But they said you need to look deeper into these other issues.

DR. RYKACZEWSKA: So, more to follow? Are there -- sorry, I didn't mean to cut off. Okay.

All right, so going back to where we were in the flow chart we'll say, okay, yes, CalHHS is engaged in this research.

The next question is, well, does it qualify for an exemption? So, of course, within the Common Rule there are several exemptions. So, we're saying, yes, this is human subjects research and it's exempt, it's one of these things that's exempt from the Common Rule review.

And so, this is just the shorthand of those. There are many documents that goes far deeper into each one of them, but at least wanted to have the shorthand.

COMMITTEE MEMBER LUND: And just to note, seven and eight, so it's a slide up, because we decided as a Committee that we would not engage in broad consent.

DR. RYKACZEWSKA: That is good to know.

VICE CHAIR DICKEY: The question is whether we can decide to do that on our own, even though it's --

COMMITTEE MEMBER LUND: It is. In the 2018 revision, broad consent is an optional thing that we can, as a Committee, decide to adopt or not.

DR. RYKACZEWSKA: Okay.

VICE CHAIR DICKEY: But a lot of the things that we review as research, such as the CHIS Survey interviews, et cetera, a lot of IRBs just say they're exempt. In fact, we've always said because of the vulnerability of our populations, et cetera, that we wouldn't consider those things to be exempt.

But that's why we get a lot of our other IRBs, so, well, my IRB said this is exempt. And we say no, but we want to review it.

DR. RYKACZEWSKA: And to the process question, the points that you made earlier, even for this staff if a researcher believes that their study is exempt, there is an

application that they have to submit. And that has to be either verified -- they can't decide on their own that they're exempt. So, it has to be verified by CPHS and approved as exempt, or they would have to submit a full, initial application.

VICE CHAIR DICKEY: Right. And those, once again they've been screened by the Chair or the Vice Chair before they can. And I -- aren't they reported on our meeting minutes, the following ones, they're considered to be exempt.

DR. RYKACZEWSKA: I believe so. The exempt ones, do they get reported in our --

MS. ATIFEH: Oh, the one that it goes on the website?

DR. RYKACZEWSKA: Uh-hum.

MS. ATIFEH: Yes. Yes.

DR. RYKACZEWSKA: Yes, okay. So, that gives me --

And this is one where our flow chart doesn't go right the yes, yes, yes mark. So, if they're not exempt, if they say no, it does not qualify for an exemption, then we review it under the Common Rule.

If it is exempt, then we would not review it under the Common Rule.

So, this one's the one that flips, and I think we thought about ten different ways of asking that question to

try to figure out how to make it clearer, but I think this was the -- this is where we landed for now, if it's not exempt then we review under the Common Rule.

COMMITTEE MEMBER LUND: I just want to say thank you. This is so much clearer that the last flow chart. And I think, you know, we've talked about where it might be refined, but I think it generally captures the process and I really appreciate all the effort that went into it.

INTERIM CHAIR DELGADO: I mean, the kudos Maggie and Agnieszka deserve in getting into the weeds in this. The clarity is, I have found it to be incredibly helpful.

Except for Allen. Allen gets minus kudos for opening up more of the doors, box issues. Just kidding, Allen.

But again, like these are questions that are, obviously, we have differing opinions, and we want to be consistent as a Committee.

So, I was just kidding. I appreciate all of those examples that folks are bringing up because it will just provide us all with more consistency.

DR. RYKACZEWSKA: All right, so that is the Common Rule side of the flow chart. There is a whole second side.

And that is the Information Practices Act. So, that's the question. So, regardless of what happens with the Common Rule, the question one, there is a second

question that has to always be asked, and that's whether CalHHS, CPHS' purview under the California Information Practices Act.

The good news is that this one has just really one box that we've got to get through. And that is, is the researcher requesting the disclosure of PII for the purposes of conducting scientific research?

COMMITTEE MEMBER LUND: I think it should say PII from a state agency.

DR. RYKACZEWSKA: Held by a state agency.

COMMITTEE MEMBER LUND: Just to clarify.

DR. RYKACZEWSKA: And that's true. And in the box next to it we do say state data is defined as, and PII held by any state agency or department. So, I think reflecting it in the question makes a lot of sense.

COMMITTEE MEMBER LUND: Okay.

DR. RYKACZEWSKA: If the answer is no, then we would not have purview under the IPA. If the answer to that question is, yes, they are requesting PII held by state data then, yes, we do. And at that point we would have purview under the IPA.

VICE CHAIR DICKEY: So, if it's not research, thought --

DR. RYKACZEWSKA: Right. So, it's for purposes of conducting scientific research.

VICE CHAIR DICKEY: Yeah. I don't know that we see any of these, but it could be that somebody wants to get state data for a purpose that maybe kind of looks like research, but it isn't really, and they have other, other uses for it.

Then, they have to go to some other section in the Information Practices Act, and not our section.

DR. RYKACZEWSKA: So, this is a -- I think we looked into this, right, Maggie, to see if the IPA had a definition of scientific research and I believe it did not.

COMMITTEE MEMBER AZIZIAN: Yeah, they don't have a specific definition in IPA of what scientific research is that we can refer to.

VICE CHAIR DICKEY: So, we're free to make that decision on our own.

MS. SCHUSTER: I mean, I think we can probably stay consistent with --

VICE CHAIR DICKEY: Just use the generalizable knowledge one. I think that's what we've been doing.

MS. SCHUSTER: Yeah.

MR. GOLDMAN: No, I don't think we can --

COMMITTEE MEMBER BAZZANO: You know, there are a bunch of other definitions from other IRBs that we can certainly look to, to clarify this and be consistent. It's

not like we're working from scratch. We can certainly, you know, check in on this and --

MR. GOLDMAN: I think it's something we can --

COMMITTEE MEMBER BAZZANO: -- it's kind of an important distinction. Yeah.

MR. GOLDMAN: We can talk about it and have conversations about it. It's not something we could issue a policy on, but it's something we could try to reach a neutral understanding of.

COMMITTEE MEMBER LUND: Is it something we could include in the regulations?

MR. GOLDMAN: Yes. Well, I'll have to think about that.

COMMITTEE MEMBER LUND: Okay, because this would be the time, if we can.

VICE CHAIR DICKEY: I guess -- I guess my point was that there are other ways people can get data. And if they can't get it through us, through the -- there are other ways they can get it through the Information Practices Act, right?

MR. GOLDMAN: Yes, that's correct.

VICE CHAIR DICKEY: There's another, like 20 other --

MR. GOLDMAN: I mean, they can just request information from the department under another exemption.

VICE CHAIR DICKEY: Right, right.

COMMITTEE MEMBER LUND: Or under those department's rules, whether or not they have IPA specific release. So, for example, if they want the data to sell tombstones that wouldn't be scientific research and it wouldn't fall under our purview.

MR. GOLDMAN: Correct.

COMMITTEE MEMBER LUND: But it would be up to the releasing agency to make sure that that complies with their state laws.

MR. GOLDMAN: Correct.

VICE CHAIR DICKEY: Yeah, and there's like all these other clauses in the IPA, yeah, pertaining to whatever. We don't need to go through them. But I don't think there's any for tombstones, specifically.

(Laughter)

DR. RYKACZEWSKA: So, I did want to just note at the bottom, I kind of briefly mentioned this, but at the end of the day just answering each of these questions is not enough. You kind of want to consider both answers.

So, if they answer yes to the first question about the Common Rule, then no to the second one, then only the Common Rule would apply to those.

Those would be incredibly rare. The only thing I could think of was if there was like an only survey, but

they're not using any administrative data --

COMMITTEE MEMBER LUND: An anonymized data file of some sort.

DR. RYKACZEWSKA: Yes, something of that nature. If they answered no to the Common Rule one, but yet to the California IPA, only the California IPA one would apply.

And if they answer yes to both, then both apply. So, this isn't an either/or, both can apply.

And finally, if they answer now to both questions, then CPHS would not have purview over this.

Any questions or concerns there?

VICE CHAIR DICKEY: We've got to get to this for context.

DR. RYKACZEWSKA: We did include the current -- what is currently in our -- in our policies and procedures, the flow chart there. And so, there's a few changes. Again, we kind of separated them out. We more intentionally spoke to how engagement in research is defined.

And so, I think, Dr. Dickey, was there -- in terms of that definition, did you want to raise that?

VICE CHAIR DICKEY: No, no. I just thought, I guess, it's time to bring this up. Right.

DR. RYKACZEWSKA: Yeah.

VICE CHAIR DICKEY: There's a disjunction between what we have in our current chart and what's in these

charts. Which is our current chart says that if we're releasing data, it's going to be used to contact human subjects because that we review under the Common Rule, which is what we have done for eons.

But it's not -- that doesn't seem to be captured in the new chart, which doesn't have a proviso if it's going to be used to contact human subjects that that makes it Common Rule.

COMMITTEE MEMBER LUND: That may be in there. I don't remember historically, it's been a long time. A number of the data sources that we commonly review require us to review under the Common Rule, like the CCR, and the birth data, and so forth actually have --

VICE CHAIR DICKEY: Yeah.

COMMITTEE MEMBER LUND: And both have in statutes, right, so we --

VICE CHAIR DICKEY: Yeah, and there may be other ones.

COMMITTEE MEMBER LUND: -- but I'm not sure about the global.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: Right. And I think Jared mentioned the department can ask for that Common Rule, the IRB review under their data releases, too, and that has been a practice.

VICE CHAIR DICKEY: So, should there be something on the chart that says one other criteria for Common Rule review is if a department requests that review under the Common Rule?

MR. GOLDMAN: This is an issue that Maggie and I have been looking at. And we might make some suggested changes to the policies and procedures down the road. We're working on that. If we could return to this issue at a future date, we'd appreciate that.

DR. RYKACZEWSKA: I do see a hand from Dr. Dinis.

COMMITTEE MEMBER DINIS: Oh, yeah, the question I have is in those cases where individuals do not see identifiers as applying to the Common Rule, and I'm not sure if this box will cover that. You know, we would go by and say, oh, yeah, they didn't -- that's not part of the Common Rule. But I think this is what comes back to that, over and over, how do you get people to recognize that identifiers don't affect the Common Rule?

DR. RYKACZEWSKA: So, I think this was what we talked about with this box right here, right that --

COMMITTEE MEMBER DINIS: Yes.

DR. RYKACZEWSKA: -- is it human subjects research. And one component of that is the personal --

VICE CHAIR DICKEY: Identifiers.

COMMITTEE MEMBER DINIS: Right, right.

DR. RYKACZEWSKA: -- the private information, identifiable by a specimen. That that automatically makes it human subjects research if it meets that definition.

And then, I think there's follow up questions for that. So, recognizing that something could be human subjects research, the next question is still, is CalHHS the ones who is engaging in that research or is it another institution where it would be their -- their responsibility to review under the Common Rule.

Is that -- okay, I'm seeing nods from Jared and Maggie.

COMMITTEE MEMBER DINIS: But that's exactly (indiscernible) -- to the IPA, where they all -- more than -- I mean, they always have, I don't know, most of the time they have identifiable private information.

DR. RYKACZEWSKA: Right. So, with the -- with the IPA side of the box agrees that personally identifiable information, right, if they're requesting that, then it definitely falls under the Common Rule.

MR. GOLDMAN: You mean the IPA.

DR. RYKACZEWSKA: I'm sorry, under the IPA. Thank you. If they are requesting PII that is held by a state -- a state agency, is the word I'm looking for, then it would fall under the IPA for sure.

Which again, I think we're trying to keep the two

separate, recognizing they're two separate laws. But Common Rule also could involve PII. And I think the question is who reviews under the Common Rule. If it does -- if it is human subjects research, if it does meet this box, then the next question ultimately is who reviews under that Common Rule.

VICE CHAIR DICKEY: Well, who's engaged.

DR. RYKACZEWSKA: And that's determined by who's engaged. Is that a fair --

COMMITTEE MEMBER LUND: And I just want to say this is great, and especially your summary at the bottom. So, we, it could be Common Rule only, for us rare. It could be Common Rule and IPA, very common. And it can be IPA only.

And I just want to note that, you know, this is a great way of pulling out all the information. Because projects that are IPA only will have another IRB, be a Common Rule consideration. And, if it weren't for the IPA, we would never even see those projects, so they wouldn't fall under our purview as Common Rule at all.

VICE CHAIR DICKEY: Right, so a lot of them. But there are those subset where we -- if they're doing interviews or contacting people with the data, and we say that makes it that we're engaged, so --

COMMITTEE MEMBER LUND: Yeah, so we need to -- I

think a refinement needs to happen around that. I agree with you that that's something that requires some --

VICE CHAIR DICKEY: I think what you've captured in the charts, which is the engagement issue, which is what always was missing in the past.

DR. RYKACZEWSKA: So, I think this is a starting point and definitely the conversation that I was hoping to have today because it is helping complicate our thinking and point to pieces of this flow chart where we really want to dig in deeper.

And so, in terms of what is even research and what is not, digging into the things that are not and making the distinction as clear as possible.

Into, similarly, in terms of this engagement piece and what falls under engagement and what doesn't, and really digging into some of this piece. More there? Uh-hum.

COMMITTEE MEMBER LUND: Oh, I just want to say one more thing before you close it out about exemptions, exempt projects.

DR. RYKACZEWSKA: Yes.

COMMITTEE MEMBER LUND: So, one of the weaknesses, I think, in the current system is that if you look at our forms that we ask the researchers to fill out, we ask them to provide the information. And the reviewers, who are generally the chairs, don't have any way, there's no check.

And I've reviewed a couple of those where people have said -- if it's, for example, like a publicly available data source that can be exempt, right, I've had people say that the birth data were a publicly available data source, right. And, actually, one of those got approved as exempt, under that exemption, and I got a call from Joshua, we don't think this is exempt.

So, I'm wondering, we may need more guidance for researchers in filling out those forms to clarify, no, just because it's publicly available that you can apply to CDPH and maybe get information, it doesn't mean that that's publicly available by our definition.

DR. RYKACZEWSKA: Uh-hum.

COMMITTEE MEMBER LUND: You know, so that kind of thing to clarify.

DR. RYKACZEWSKA: Definition clarification of what's publicly available.

COMMITTEE MEMBER LUND: Yeah. For those items because, you know, they may not know. You may be asking researchers to provide us with information that they, themselves, are not clear about or don't have.

DR. RYKACZEWSKA: All right, thank you.

VICE CHAIR DICKEY: And then, you know, the whole workflow process is it should stop with the Chair or Vice Chair, or should there be a subcommittee that just looks at

the exemptions or something like that.

COMMITTEE MEMBER LUND: Yeah, a subcommittee of more than two people requires a public meeting and that can be a problem. I don't know, I think it's worth exploring because I do think it's a lot of burden on Chairs, and to me it doesn't really offer a lot of diversity in terms of eyes looking at the things, so --

VICE CHAIR DICKEY: Yeah. I mean, traditionally it's been I think, you know, both the Chair and the Vice Chair that have looked at some of this and asking each other back and forth to agree. But there's nothing that says that has to happen.

DR. RYKACZEWSKA: All right, another topic to add to our list, which is good.

Any final comments? Any public comments on this agenda item. And I'll stop screen sharing so I can see the public comments, if there are any.

I do not see any virtual hands. Any hands in the room, Nick?

MR. ZADROZNA: No comments in person.

DR. RYKACZEWSKA: No comments in person. And I'm giving just another moment for any virtual hands.

COMMITTEE MEMBER VENTURA: Are there not comments in the chat? I saw two.

DR. RYKACZEWSKA: Okay, I am not seeing any

comments in chat, so now I'm worried.

COMMITTEE MEMBER HESS: Yeah, there it is.

COMMITTEE MEMBER VENTURA: Two. Yeah, two. Click on chat, there you go.

DR. RYKACZEWSKA: Oh. Oh, these are -- ah, okay. Thank you.

COMMITTEE MEMBER HESS: Yeah, I don't know if these are public.

DR. RYKACZEWSKA: So, Francis is one of our -- she's helping us with our meeting minutes. And so --

MS. BROWN: Oh, and that was -- it's okay. One of them got -- you know, it's okay, it's okay. I can get clarification later from like -- it's fine.

DR. RYKACZEWSKA: Okay, we will follow up on those definitions.

VICE CHAIR DICKEY: And the other question is how do we confirm destruction of data, which I think is a whole other topic.

DR. RYKACZEWSKA: Any further comments?

INTERIM CHAIR DELGADO: We're getting there, guys.

DR. RYKACZEWSKA: I'm not seeing any, anywhere.

INTERIM CHAIR DELGADO: Okay.

DR. RYKACZEWSKA: I think I'm way over time. But I think really valuable discussion and I really do appreciate the feedback, it's really helpful.

INTERIM CHAIR DELGADO: And again, thank you guys. Thank you and Maggie for the work on it.

Okay. Powering through, Agenda Item E. I'm going to hand it over to Agnieszka. Agnieszka's going to be providing an update on continuing education. I will just say, again, thank you to the admin team for their work. Thank you, Maggie and Jared for being here.

Thank you all for the work in looking into these continuing education. I just want to acknowledge, before we get into the topic, that in previous meetings I think I said publicly, was talking about a mandatory nature related to continuing education.

I think what you're about to hear from Agnieszka is that the scope of trainings and the amount of time is a lot different than when I originally thought it was like a one-hour, one-time training.

So, just acknowledging that I have said that in the past, not understanding the full scope of what Agnieszka's about to talk about. So, take it with a grain of salt.

Okay, handing it over.

DR. RYKACZEWSKA: Thank you. And just a moment because I want to make sure I'm pulling up the right thing.

VICE CHAIR DICKEY: And, traditionally, there's been something in our policies and procedures that has said,

has referred to, and it would be worth looking at that, about members or new members about having to do a certain amount of training, and whether we want to continue that, or change it, or whatever.

It's traditional. I think most research institutions do require researchers to complete some training on this stuff. And their IRBs tend to enforce it. We've never done that because we've always figured the other IRBs were doing it, plus we hadn't done it ourselves.

DR. RYKACZEWSKA: Yes.

VICE CHAIR DICKEY: So, but I think this whole discussion about what is engagement of research, et cetera, et cetera shows how complex the rules are. And it would be helpful if the Committee as a whole knew some of the complexity of the rules, rather than just a few people.

DR. RYKACZEWSKA: And so, with that I'm going to start with what's in our policies and procedures. So, within the policies and procedures there is a requirement that all new members must complete the Human Research Protection Foundation training found online at this link.

And so, what that covers, just so we're clear -- and I pulled it up. Of course, it's not sharing the right page. Here we are, okay.

So, this -- this is the training that that references. This is the Foundation's training from OHRP.

It is about five and a half -- a little under five and a half hours long and includes five lessons. So, that is when do the HHS regulations apply. What is human subjects research. What are IRBs. The IRB review of the research. And institutional oversight of human subjects research.

So, that is the training that is currently within our policies and procedures that all members should complete.

VICE CHAIR DICKEY: It says all new members.

DR. RYKACZEWSKA: All new members. So, at least once, when they join, everybody should complete that.

VICE CHAIR DICKEY: We were all a new member at some point.

DR. RYKACZEWSKA: That's right. And so, just wanted to start with that as here is our starting point is, here's where our current requirements are.

Now, at the beginning of the year the request was made both by the Chairs, and also through conversations with many of the Committee members saying it would be really useful to have additional training resources to get into some of these things.

And so, after exciting, I'm going to use the term exciting procurement journey, we were able to procure the Citi trainings to be available as a resource to Committee members, to the admin team as well.

And we have actually confirmed that we can set up the accounts, that's already to go to be shared with Committee members after this meeting.

But I did want to touch base and review what those trainings are and review some recommendations for what might be updated in terms of -- or, what might be requirements for you leveraging those trainings.

VICE CHAIR DICKEY: So, would this be in addition to the requirement we have for the foundational --

DR. RYKACZEWSKA: I think to be discussed.

VICE CHAIR DICKEY: Okay.

DR. RYKACZEWSKA: I'm curious what the Committee feels. I don't know.

But let me at least cover what is available through the Citi trainings. Let me pull that up and share it on the screen. Here we go.

Okay. So, through the Citi training we have available six trainings of various lengths and content. Now, the first one of these is the IRB member training. This is quite a large training. I'm going to go ahead, and it goes really in-depth to many of the things that an IRB member might encounter through their reviews.

This training is between 15 to 20 hours long. So, much more than the current training that we have in our policies and procedures right now. The reason there is

variation in the timing is that it does include 40 supplemental modules on various different topics that really dig really deep into those particular topics. Those are optional. So, the core training should take about 15 hours. And then, if you do the additional modules, then that would be the additional time.

In addition, there is also an IRB protocol review. So, this is suggested for audiences that are directly involved in review of non-exempt human subjects research. And so, that talks through things like the review criteria and those types of things. That is an additional two hours.

There is a quality assurance, quality improvement human subjects research section.

There's one on information privacy and security.

And a final one on -- sorry, two more. There's becoming an effective leader.

And then, finally, IRB administration comprehensive. That is another five to six hours.

So, sorry, I recognize I'm going quickly through all these because I'm trying to keep our time in mind and know that many Committee members might need to go so.

But at least wanted to cover our recommendations, that we would say that the required ones from the Citi trainings would be this IRBManager -- excuse me, IRB member, and the information privacy and security one.

So, for IRB member, I think we would only require just the core, not necessarily those 40 supplemental pieces. If that's the case, that would be 16 hours total for these two trainings.

And then, should others, the optional pieces be added, that would be a 22-hour total.

And then, the remaining trainings would be there as options for Committee members should they want to pursue any of those additional topics.

For our admin staff, we are recommending that they be required to be the IRB administration comprehensive, as well as the IRB protocol review, so that they can be keeping in mind those pieces as well.

So, I'm going to pause there and just open it up for feedback. I know this is a big commitment that we're proposing, and so wanted to see what are thoughts.

COMMITTEE MEMBER HESS: I can say that as a researcher I've done both the OHRP and the Citi trainings, and the Citi trainings are far more useful, more comprehensive. They answer more questions. They're kind of -- if we're like looking at like should we require Citi training, instead of OHRP, for new members, yes, it's a bigger time burden, but it's a superior training, I think.

VICE CHAIR DICKEY: So, you go along with that recommendation for the Chair and Co-Chair?

(Laughter)

COMMITTEE MEMBER HESS: I mean, yeah. You know, it goes so much deeper than the OHRP training.

VICE CHAIR DICKEY: Uh-huh.

COMMITTEE MEMBER HESS: That I think it's just far more useful.

DR. RYKACZEWSKA: I see a hand from Dr. Schaeuble.

COMMITTEE MEMBER AZIZIAN: Is there a timeline? I think members -- oh, sorry.

VICE CHAIR DICKEY: That's from Dr. Azizian.

DR. RYKACZEWSKA: Oh, sorry, Dr. Azizian. Dr. Schaeuble and then Dr. Azizian.

COMMITTEE MEMBER SCHAEUBLE: I think the question in all of this, for me at least, is about that word "required", rather than saying suggested, or strongly recommended, or something of that sort.

And maybe I shouldn't be saying it, but I look into my future life here and to set aside up to 22 hours for something more, on top of things that I'm already doing, I don't see those hours being available. I just don't. And that would make the word "required" not really workable for me.

DR. RYKACZEWSKA: I am recognizing the volunteer basis, as I think we've discussed before, of the Committee members.

VICE CHAIR DICKEY: So, this would only be required of state employees?

(Laughter)

DR. RYKACZEWSKA: But acknowledging, Dr. Dickey, that the --

VICE CHAIR DICKEY: No, I understand, it's being in the same boat but --

DR. RYKACZEWSKA: Well --

VICE CHAIR DICKEY: You've done this. Were you required to do this for other IRBs?

COMMITTEE MEMBER HESS: Yeah, as a researcher for other IRBs I was required to have Citi training before I could submit a protocol.

VICE CHAIR DICKEY: Oh, yeah.

COMMITTEE MEMBER DINIS: Yeah, Sac State does this, too, but they only have like one- or two-hour trainings. And so, you know a much shorter version. So, this just seems like a lot, you know, to -- or somebody can go in there and see whatever it is they think they are more weak on and they want to review, maybe. I'm just trying to figure out how we can make it so it's not so cumbersome.

DR. RYKACZEWSKA: And Dr. Azizian, I know that you had a comment as well.

COMMITTEE MEMBER AZIZIAN: Yeah, along the same lines. I was just wondering if there's a timeline that this

is encourage or required. I'm just generally speaking as a licensed psychologist I have to do continuous education already for that, and some other certifications. And 20 hours of additional training, well, is there a timeline for when this is supposed to be completed?

DR. RYKACZEWSKA: We haven't discussed one and we would certainly be amenable to a very flexible timeline, I think, recognizing that it is quite a bit.

COMMITTEE MEMBER LUND: So, I think it's a lot to require both OHRP and Citi. And I would defer to the recommendation that Citi is better. I mean, if we're going to optimize our time, if I'm going to put time into it, I mean I would rather do the one that's going to yield the most benefit.

So, if we're going to adopt Citi, perhaps we could remove the requirement for the OHRP.

I do see the problem with requiring volunteers to invest this much time. On the other hand, to play devil's advocate, the work we do is really, really very important and it's very difficult to do if you're not educated about it.

We actually make a difference in, you know, whether or not researchers are able to get their work done and whether or not human subjects are adequately protected.

So, I would think that it would be good for

everybody to do this. I, personally, have not had the Citi training and would be interested in doing it. But is it possible to say within the next year complete your 22 hours.

DR. RYKACZEWSKA: Yes.

COMMITTEE MEMBER LUND: I think that's -- or 16 hours. I think that's a reasonable time frame. People can go at their own pace. That seems like it would be reasonable to me.

VICE CHAIR DICKEY: So, that would be for current members or future members they'd have like a year to --

COMMITTEE MEMBER LUND: Yeah, I would -- I would say that. I think it's something that everybody should do, you know, regardless of whether or not you've been on the Committee -- you're not new, I guess. I think this stuff is really important.

VICE CHAIR DICKEY: So, is there a certificate produced by --

DR. RYKACZEWSKA: Yeah.

COMMITTEE MEMBER HESS: Yeah, and it's the really widely used one in research.

COMMITTEE MEMBER VENTURA: Most of the Citi trainings provide certifications for like three years.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER VENTURA: And then, you need renewal, at least for researchers, like the human subjects

type training you have to renew every three years. So, it's a refresher, it's an assurance that you're going to do continuing education and just refresh.

There's also a full course and refreshers, so --

COMMITTEE MEMBER HESS: Yeah, the refresher courses are pretty minimal.

COMMITTEE MEMBER VENTURA: Right, minimal.

COMMITTEE MEMBER HESS: And they do, I mean they go over changes. Like I took -- I had to take Citi training again after the 2018 changes and it was really useful because, otherwise, I wouldn't have quite maybe educated myself as a researcher about the changes around the Common Rule. And it's useful.

INTERIM CHAIR DELGADO: And that's why, like to mandate and give a date, then we'd, us all to wait until the day before, and do the quick through without really digesting the information and having it be useful the way that you've described, so --

COMMITTEE MEMBER HESS: Citi doesn't let you do this like through.

VICE CHAIR DICKEY: You have to do it.

COMMITTEE MEMBER HESS: You have to actually like pay attention and interact. I mean it's --

COMMITTEE MEMBER VENTURA: There's quizzes, really.

COMMITTEE MEMBER HESS: Quizzes, yeah.

COMMITTEE MEMBER VENTURA: Throughout the module, so you can't like just tune out and wait until the end, and then --

VICE CHAIR DICKEY: So, I'm going to suggest something. I know it sounds outrageous, but is there any possibility in the world that the agency could reimburse volunteers for their training time for this?

DR. RYKACZEWSKA: I do not know, but I can look into it.

VICE CHAIR DICKEY: I mean, it would be -- given the fact that as volunteers work for nothing, anyway, it would seem the least they could do is reimburse something for our time for training.

DR. RYKACZEWSKA: I can look into it.

COMMITTEE MEMBER VENTURA: Especially if it's required.

VICE CHAIR DICKEY: If it's required.

INTERIM CHAIR DELGADO: Agnieszka is being -- Agnieszka is being kind in saying that she will look into it, which I totally appreciate. I will tell you, at a broader scale from the budget cuts that we're facing, it's probably not likely.

VICE CHAIR DICKEY: I understand.

INTERIM CHAIR DELGADO: But I trust that Agnieszka

will look into it.

VICE CHAIR DICKEY: That's why I said it was outrageous then.

COMMITTEE MEMBER SCHAEUBLE: So, I'll ask the other question. If it's going -- if it's required and I don't have those 22 hours, am I going to be kicked off the Committee?

VICE CHAIR DICKEY: Well, that's the --

COMMITTEE MEMBER LUND: What's the enforcement, right, yes.

VICE CHAIR DICKEY: That's the question.

DR. RYKACZEWSKA: I do not have any recommendation on that. But what are our thoughts?

COMMITTEE MEMBER HESS: Can we look into, and I don't recall what Citi training like -- once you get an account, can you go -- can you do two hours a week, an hour a week?

COMMITTEE MEMBER VENTURA: Yes.

COMMITTEE MEMBER HESS: You can. I can't remember.

COMMITTEE MEMBER VENTURA: Yes. I mean, you can do one module at a time. You can't pause, I don't think, in the middle of a module.

COMMITTEE MEMBER HESS: No, but --

COMMITTEE MEMBER VENTURA: But you have to at

least do, say, commit to whatever, 30 minutes or one hour to just do that one, and then save your place and come back and complete.

COMMITTEE MEMBER HESS: Yeah, you can do it. It's not like you need to have a week where you're doing 22 hours. You can do it --

COMMITTEE MEMBER VENTURA: You could do one hour, 30 minutes, some of them are short.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER VENTURA: And then others are a little bit longer.

COMMITTEE MEMBER HESS: Yeah.

COMMITTEE MEMBER VENTURA: But yeah, you could spread this out for sure.

COMMITTEE MEMBER HESS: Yeah.

VICE CHAIR DICKEY: We could all take 30 minutes out of every meeting, and we could --

(Laughter)

COMMITTEE MEMBER VENTURA: And watch the video.

VICE CHAIR DICKEY: Just do it. That might help us to actually get it done but --

DR. RYKACZEWSKA: Group study. Group study.

VICE CHAIR DICKEY: Yeah.

DR. RYKACZEWSKA: Other questions, other thoughts? This is marked as an action item on the agenda. That said,

I'm already hearing that there are things for us to look into before we would be really be able to take an action on this item. So, perhaps I can go look into some of the things and come back.

VICE CHAIR DICKEY: I just wanted to add that it used to be, you know, 25 years ago, all Committee members got a subscription to, you know, to a journal that talked -- you know, for IRB stuff. And there was actually built in funds for that. And there were also funds for going to conferences.

Now, I know none of us go to conferences but, you know, at least we used to do much more of this and I think it resulted in the Committee being much more on a common ground because we all were kind of speaking the same language.

DR. RYKACZEWSKA: What I'm taking away right now is that we are seeing that it could be useful. There's a question of is it required or is it strongly encouraged is one aspect of it. And what would be the implications if it is required.

And there's this question of can there be some reimbursement. Acknowledging our current budget circumstances that that might be very unlikely, but I can certainly ask.

VICE CHAIR DICKEY: Don't forget the idea of just

us doing it in a meeting. We're going to do one section in a meeting.

DR. RYKACZEWSKA: We're doing it together, then.

VICE CHAIR DICKEY: We're doing it as a group.

DR. RYKACZEWSKA: A group.

COMMITTEE MEMBER HESS: Can we do that? The way the Citi system is set up, because it's an individual account.

COMMITTEE MEMBER VENTURA: You have to take your test and earn your individual certification.

COMMITTEE MEMBER HESS: Yeah.

VICE CHAIR DICKEY: Right, but we could have one person have that account. All the Committee members would be -- would just have to come to the meetings. And that at the end, if you come to the meetings, you would have gotten it.

COMMITTEE MEMBER LUND: Yeah, but what if you miss a meeting or --

VICE CHAIR DICKEY: Well, I don't know. How strict are we going to be about this, you know, I mean --

COMMITTEE MEMBER LUND: Yeah.

DR. RYKACZEWSKA: All right. Well, we'll pick this one up, then, at a future meeting after we have a chance to look into. But if you have additional thoughts, please do let me know, or additional ideas of how to

approach. Very open to it.

Any public comments on this item? Sorry, do you want me to -- Nick, any public comment?

MR. ZADROZNA: No public comments in person.

DR. RYKACZEWSKA: No public comments in person. And I am not seeing any virtual hands. Going once, going twice.

So, I believe with that I can hand it back to Darci.

INTERIM CHAIR DELGADO: Okay, thank you everyone.

Okay, so Agenda Item F, I just want to acknowledge that we have received public comment letters. We should be passing them along to everyone via email, as part of the -- if they're sent in time, as part of the documents related to today's meeting or whatever meeting those letters are preceding.

If not, there are physical copies in your binder today. And I believe they were emailed out as part of the information submitted for today's meeting.

But just want to acknowledge that there were written comments received from Robert Fairlie, Eric McGhee, Paulette Cha, Vincent Quan, Amy Finklestein, Matt Notowidigdo, and Laura Feeney.

And so, would just continue to encourage those who are listening in, or those who turn in afterwards for the

public comments, that they continue to do so because the Board is very interested in continuing to engage with the public on these topics.

Yes?

COMMITTEE MEMBER LUND: Laura here. I just want to say public comment is always welcome and I think the process is strengthened by public comment. I would like to say that as a member of the subcommittee, and also of CPHS, I'm concerned with the level and scope of misinformation that appears to be circulating in the researcher community around this group's efforts and the subcommittee's efforts to develop regulations for the IPA.

I would like to be very clear, so that people can reference back to this meeting, that the Committee is not entertaining going back and retroactively obtaining informed consent for people whose information was collected in state administrative databases.

We are not changing anything about Common Rule review of projects.

The intention of the regulations is strictly to help clarify how projects that are IPA only projects are reviewed. And that we have not yet developed regulations, which also appears to be a piece of misinformation that's out there.

We have developed or are still developing,

finalizing a document that provides the underpinnings for how we would approach reviews of IPA projects and what we would consider in those reviews, but we have yet to develop any regulation language at all.

So, I just would like to be really clear for the public that there seems to be misinformation circulating. And I would like the misinformation to not circulate. And people are welcome to attend and hear the discussion of the subcommittee. I would encourage people who are concerned about the regulations to hear that, because I think you would hear something very different than what is apparently being circulated in the researcher community about what's at those committee meetings.

And I would invite -- Ms. Kurtural isn't here but, you know, either Dr. Schaeuble or Dr. Dinis, if they have anything they'd like to add to that as other subcommittee members.

COMMITTEE MEMBER SCHAEUBLE: Yes, I would add a bit to that because I've noticed in many of the communications we have received assertions to the effect that members of the all of CPHS, and/or members of the subcommittee have a goal in mind of rejecting whole categories of research that -- assertions to the effect that the Committee wants to stop any research for which nothing may be known about what was told to individuals at the time

data were collected, or any research that involves linking data to other data in some particular way.

And those statements are simply not grounded in reality. That is not what we have been about. And they really muddy the waters as far as any understanding of concerns that researchers may otherwise have.

INTERIM CHAIR DELGADO: Well, I would encourage -- oh, sorry.

COMMITTEE MEMBER SCHAEUBLE: No, I'll stop.

INTERIM CHAIR DELGADO: Okay. I would encourage repeating this communication and these thoughts at your next subcommittee meeting, to start it off with that. Because I -- I feel like I've communicated some of the same in this public meeting, particularly just, in my opinion, me, as Darci, the hyperbolic nature of some of the comments made, and the trust that I have in the subcommittee process and the regulations process, should that be the ultimate avenue.

And would just encourage us to communicate that as much as possible to members of the public.

I know Jared is communicating that when he meets with folks individually, who express concerns to him as general counsel, and he will continue to do so.

I would encourage all of us to do that because I think that the good faith efforts that we are partaking in have great benefit in the long run, but also can be very

thick mud to trudge through to get to that ultimate destination.

VICE CHAIR DICKEY: I'd just like to make a statement. I would also urge you, though, to take their comments seriously and not dismiss them. You know, researchers' livelihoods depends on their ability to get the data that they need for research.

And you can say that you're not going to go back and require informed consent. I understand that's not possible. But you could use the fact that they didn't get informed consent before as a reason for rejecting it.

And that is, you know, leaving that big window open for them is very threatening.

COMMITTEE MEMBER LUND: I understand that. And I do understand. In fact, I think I spoke just half an hour ago about how what we do matters for researchers, it's their livelihood being able to do this researcher.

And the subcommittee has not discussed, and this is again the misinformation that's circulating, we have not discussed rejecting applications because informed consent wasn't initially obtained.

We have asked what was told to people about their data and that we would like to know that. But, you know, so I think it's really, really important that what is shared with researchers is what is actually being discussed and

considered at the subcommittee meeting, rather than second and third hand, you know, twisted information.

And I believe that we're very respectful in that meeting of the research process and the needs of both the human subjects, the people whose data are being used, and of the research review process and what's reasonable, and not stepping beyond the bounds of what's reasonable in the situation.

And so, I just -- my concern is with -- and even hearing you say, you know, don't dismiss their concerns, I don't believe we have dismissed their concerns when they're concerns are founded in the reality of what we're actually doing. But when there's second and third hand misinformation out there those are concerns that -- we can't track down the misinformation and make sure that people are getting the correct information unless they actually come to the subcommittee, or read the transcripts from the subcommittee, and not what they've been told second or third hand. So, that's my concern.

VICE CHAIR DICKEY: Yeah, and think that just -- and, you know, we need to make sure people know when the meetings are and, you know, make sure they know.

You know, it's Russian bots are behind this.

COMMITTEE MEMBER LUND: Well, you know, I told Dr. Schaeuble, you would think that the Russians worked on the

subcommittee because of the amount of misinformation that's been circulating out there. So, yes, I -- they are publicly posted, they're subject to Bagley-Keene, so there's agendas in advance. People, we have opportunities for the public to attend. They do attend. We do queue them when they want to speak. So, you know, it's all being done transparently and out in the open.

DR. RYKACZEWSKA: And just a reminder, there is a subcommittee meeting next Friday, on November the 8th.

COMMITTEE MEMBER LUND: Nice segue.

DR. RYKACZEWSKA: Okay, I want to pause for a second to see if there's any public comment on this item. I'm not seeing any virtual hands.

Nick, any in the room?

MR. ZADROZNA: None in person.

DR. RYKACZEWSKA: None in person. Yep.

INTERIM CHAIR DELGADO: Great. Okay, so I will move to adjourn the meeting. As mentioned, the subcommittee will be meeting next week, Friday, November 8.

And the next meeting for the full board is Friday, December 6.

The meeting is adjourned. Thank you all.

(Thereupon, the meeting was adjourned at 11:29 a.m.)

--oOo-

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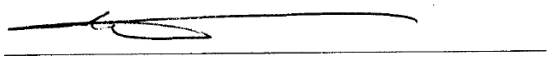

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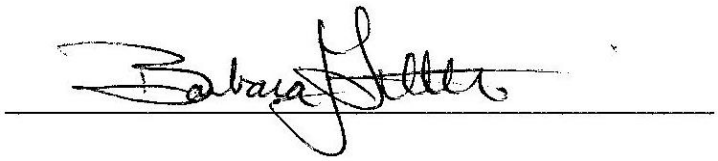

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